UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

LORETTO HOSPITAL OF CHICAGO,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; ABBOTT LABORATORIES; ABBOTT LABORATORIES, INC.; MCKESSON CORPORATION; CARDINAL HEALTH, INC.; AMERISOURCEBERGEN DRUG CORPORATION; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; ANDA, INC.; H.D. SMITH, LLC f/k/a H.D. SMITH WHOLESALE DRUG CO.; HENRY SCHEIN, INC.; DEPOMED INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; SPECGX, LLC; INSYS THERAPEUTICS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; and MIAMI-LUKEN, INC.	)	**Civil Action No. 1:19-cv-1375** **JURY TRIAL DEMANDED**
	)	
Defendants.	)	

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COMPLAINT

Plaintiff LORETTO HOSPITAL OF CHICAGO, by and through its attorneys, hereby files its Complaint against the Defendants and state as follows:

I. INTRODUCTION

1. The United States is in the midst of an opioid[1] epidemic caused by Defendants' unlawful marketing, sales, and distribution of prescription opioids that has resulted in addiction, criminal activity, serious health issues, and loss of life.

2. Plaintiff brings this civil action to recover past and future monetary losses that have been incurred or will be incurred as a direct and proximate result of Defendants' false, deceptive, and unfair marketing and/or unlawful diversion of prescription opioids. Such economic damages were foreseeable to Defendants and were sustained because of Defendants' unlawful actions and omissions.

3. Opioid analgesics were widely diverted and improperly used, and the widespread abuse of opioids has resulted in a national epidemic of opioid overdose deaths and addictions.[2]

4. The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[3]

5. Plaintiff brings this suit against the pharmaceutical manufacturers of prescription opioids. The manufacturers aggressively pushed highly-addictive, dangerous opioids, falsely representing to medical providers that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded medical providers to

[1] As used herein, the term "opioid" refers to the entire family of opiate drugs, including natural, synthetic, and semi-synthetic opiates.
[2] *See* Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain-Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 1253 (2016).
[3] *See* Robert M. Califf *et al.*, *A Proactive Response to Prescription Opioid Abuse*, 374 N. Eng. J. Med. 1480 (2016).

prescribe highly addictive, dangerous opioids, and turned patients into drug addicts for their own corporate profits. Such actions were unlawful.

6. Plaintiff also brings this suit against the wholesale distributors of these highly addictive drugs. The distributors and manufacturers unlawfully breached their legal duties under federal law to monitor, detect, investigate, refuse, and report suspicious orders and the diversion of prescription opiates.

7. The distribution and diversion of opioids throughout the United States, including Chicago, Illinois, and in the communities serviced by Plaintiff's hospitals created the foreseeable opioid crisis for which Plaintiff here seeks relief.

8. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which Plaintiff seeks relief. Categories of past and continuing sustained damages include, *inter alia*: (1) costs, including increased operational costs, for providing medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling, and rehabilitation services; and (3) costs for providing treatment of infants born with opioid-related medical conditions. These damages have been suffered, and continue to be suffered, directly by Plaintiff.

II. PARTIES

A. PLAINTIFF

9. Plaintiff LORETTO HOSPITAL OF CHICAGO. LORETTO HOSPITAL OF CHICAGO has a principal place of business located at 645 S. Central Avenue, Chicago, Illinois 60644. In the last decade, LORETTO HOSPITAL OF CHICAGO experienced [√] emergency

department visits, [√] inpatient admissions, [√] outpatient hospital visits, and [√] newborn deliveries.

B. DEFENDANTS

1. Pharmaceutical Defendants

10. The Pharmaceutical Defendants are defined below. At all relevant times, the Pharmaceutical Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Pharmaceutical Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

11. Purdue Pharma L.P. is a limited partnership organized under the laws of Delaware. Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut, and The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue"). Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER throughout the United States and in each community in which Plaintiff's hospitals are located. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

12. Abbott Laboratories is an Illinois corporation with its principal place of business in Abbott Park, Illinois. Abbott Laboratories, Inc. is a subsidiary of Abbott Laboratories, whose

principal place of business is also in Abbott Park, Illinois. Abbott Laboratories and Abbott Laboratories, Inc. are referred to collectively as "Abbott." Abbott was primarily engaged in the promotion and distribution of opioids nationally due to the co-promotional agreement with Purdue. Namely, in 1996, Purdue made a deal with Abbott that Abbott's sales force would promote Purdue's lead opioid, OxyContin, in hospitals.[4] Pursuant to that agreement, between 1996 and 2006, Abbott actively promoted, marketed, and distributed Purdue's opioid products. Abbott, as part of the co-promotional agreement, helped turn OxyContin into the largest selling opioid in the nation. Under the co-promotional agreement with Purdue, the more Abbott generated in sales, the higher the reward. Specifically, Abbott received twenty-five to thirty percent (25-30%) of all net sales for prescriptions written by doctors its sales force called on. This agreement was in operation from 1996-2002, following which Abbott continued to receive a residual payment of six percent (6%) of net sales up through at least 2006. With Abbott's help, sales of OxyContin went from a mere $49 million in its first full year on the market to $1.2 billion in 2002. Over the life of the co-promotional agreement, Purdue paid Abbott nearly half a billion dollars. Upon information and belief, Abbott was intimately involved in all of Purdue's marketing conduct, as specifically set forth in this Complaint, through the co-promotional agreement.

13. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora throughout the United States and in each community in which Plaintiff's hospitals are located. Actiq and Fentora have been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and

[4] *See, e.g.*, 2002 Purdue Budget Plan, available at https://khn.org/news/purdue-and-the-oxycontin-files/ (last visited Apr. 30, 2019) ("In an effort to continue gaining hospital []formulary acceptance of OxyContin Tablets, representatives will work with their Abbott counterparts to make calls on all Pharmacy and Therapeutic committees.").

who are tolerant to opioid therapy for their underlying persistent cancer pain."[5] In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.[6]

14. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a wholly-owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

15. Teva Ltd., Teva USA, and Cephalon collaborate to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the U.S. through Teva USA. Teva Ltd. and Teva USA publicize Actiq and Fentora as Teva products. Teva USA sells all former Cephalon-branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold throughout the United States and in Chicago, Illinois, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed throughout the United States and in Chicago, Illinois, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon's promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.'s logo.[7] Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as

[5] Highlights of Prescribing information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf; Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021947s013lbl.pdf.

[6] Press Release, U.S. Dep't of Justice, *Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html.

[7] *E.g.*, *ACTIQ* (Feb. 2017), http://www.actiq.com/(displaying logo at bottom-left).

its own.[8] Through interrelated operations like these, Teva Ltd. operates throughout the United States and in Chicago, Illinois through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business itself throughout the United States and in Chicago, Illinois. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Ltd., Teva USA, and Cephalon, Inc. are hereinafter collectively referred to as "Cephalon.")

16. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Noramco, Inc. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J hereinafter are collectively referred to as "Janssen."). Janssen manufactures, promotes, sells, and distributes drugs throughout

[8] Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), https://www.sec.gov/Archives/edgar/data/818686/000119312514041871/d649790d20f.htm.

the United States and in each community in which Plaintiff's hospitals are located, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

17. Depomed, Inc. ("Depomed") is a California corporation with its principal place of business in Newark, California. Depomed describes itself as a specialty pharmaceutical company focused on pain and other central nervous system conditions. Depomed develops, markets, and sells prescriptions drugs in Chicago, Illinois and across the United States. Depomed acquired the rights to Nucynta and Nucynta ER for $1.05 billion from Janssen pursuant to a January 15, 2015, Asset Purchase Agreement. This agreement closed on April 2, 2015.

18. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly- owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. hereinafter are collectively referred to as "Endo.") Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States and Chicago, Illinois. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products throughout the United States and in Chicago, Illinois, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

19. Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the

combined company changed its name to Allergan PLC in January 2013. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013, later to Actavis PLC in October 2013. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan PLC, which uses them to market and sell its drugs throughout the United States and in Chicago, Illinois. Upon information and belief, Allergan PLC exercises control over and derives financial benefit from the marketing, sales, and profits of Allergan/Actavis products. (Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. hereinafter are referred to collectively as "Actavis.") Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, throughout the United States and in each community in which Plaintiff's hospitals are located. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

20. Mallinckrodt, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its American headquarters in St. Louis, Missouri. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, PLC. SpecGx,

LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly owned subsidiary of Mallinckrodt, PLC. Mallinckrodt, PLC, Mallinckrodt, LLC, and SpecGx, LLC are referred to as "Mallinckrodt." Mallinckrodt manufactures, markets, and sells drugs, including generic oxycodone, of which it is one of the largest manufacturers in the United States.

21. Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys manufactures and sells the opioid medication known as Subsys. Insys has engaged in the sale of Subsys throughout the United States and in Chicago, Illinois. Subsys is a liquid formulation of fentanyl to be applied under the tongue, also called a sublingual spray. It was approved by the FDA in 2012. Subsys is classified as a Schedule II drug under the Controlled Substances Act. Upon information and belief, Insys revenues are derived almost entirely from sale of the Subsys product.

2. Distributor Defendants

22. The Distributor Defendants also are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing the United States.

23. McKesson Corporation ("McKesson") has its principal place of business in San Francisco, California and is incorporated under the laws of Delaware. During all relevant times, McKesson operated as a licensed pharmacy wholesaler in the State of Illinois and has distributed

substantial amounts of prescription opioids to providers and retailers throughout the United States and in Chicago, Illinois.

24. Cardinal Health, Inc. ("Cardinal") has its principal place of business in Ohio and is incorporated under the laws of Ohio. During all relevant times, Cardinal operated as a licensed pharmacy wholesaler in the State of Illinois and has distributed substantial amounts of prescription opioids to providers and retailers throughout the United States and in Chicago, Illinois.

25. AmerisourceBergen Drug Corporation ("AmerisourceBergen") has its principal place of business in Pennsylvania and is incorporated under the laws of Delaware. During all relevant times, AmerisourceBergen operated as a licensed pharmacy wholesaler in the State of Illinois and has distributed substantial amounts of prescription opioids to providers and retailers throughout the United States and in Chicago, Illinois.

26. Anda, Inc., ("Anda") through its various DEA registrant subsidiaries and affiliated entities, including but not limited to, Anda Pharmaceuticals, Inc., is the fourth largest distributor of generic pharmaceuticals in the United States. Anda is a Florida corporation with its principal place of business in Weston, Florida. In October 2016, Defendant Teva acquired Anda from Allergan plc (i.e. Actavis), for $500 million in cash. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States and in Chicago, Illinois.

27. H. D. Smith, LLC f/k/a H. D. Smith Wholesale Drug Co. ("H. D. Smith") through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the United States, including Chicago, Illinois and the communities served by Plaintiff. H. D. Smith is a privately-held independent pharmaceuticals distributor of wholesale brand, generic and specialty pharmaceuticals and is a Delaware corporation with its principal place of business in Illinois. H. D. Smith, LLC's sole member is H.

D. Smith Holdings, LLC, and its sole member is H. D. Smith Holding Company, a Delaware corporation with its principal place of business in Illinois. H. D. Smith is the largest independent wholesaler in the United States. In January 2018, AmerisourceBergen acquired H. D. Smith.

28. Henry Schein, Inc. (Henry Schein) describes its business as providing a products and services to integrated health systems, designed specifically for and focused exclusively on, the non-acute care space. Henry Schein is incorporated in Delaware, with its principal place of business located in Melville, New York. Henry Schein distributes, among other things, branded and generic pharmaceuticals and was in the business of distributing, and redistributing, pharmaceutical products to consumers within Chicago, Illinois. In 2015, Henry Schein reported that its sales reached a record $10.4 billion and that it had grown at a compound annual rate of approximately 16 percent since becoming a public company in 1995.

29. Miami-Luken, Inc. ("Miami-Luken") is an Ohio corporation with its headquarters and principal place of business in Springboro, Ohio. At all times relevant to this Complaint, Miami-Luken distributed prescription opioids throughout the United States, including in Chicago, Illinois.

III. JURISDICTION AND VENUE

30. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1407 and Case Management Order One ¶ 6(a), *In Re: National Prescription Opiate Litigation*, No. 1:17-CV-2804 (N.D. Ohio, Apr. 11, 2018), ECF No. 232.

31. This Complaint is being filed directly into the multidistrict litigation in this District with case name *In Re: National Prescription Opiate Litigation* (No. 1:17-CV-2804), pursuant to the procedure outlined in Paragraph 6(a) of Case Management Order One entered in that case.

32. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 based upon

the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq*. This Court has supplemental jurisdiction over Plaintiff's Illinois state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

33. This Court has personal jurisdiction over Defendants. Defendants have engaged in conduct and activities over a long time, systematically, individually, jointly and severally, that have caused the damages of Plaintiff, all of which form the bases of the causes of action in this Complaint. Defendants have committed multiple torts and breaches throughout the United States, including in Ohio, repeatedly and systematically. Defendants, for a long time, repeatedly and systematically, have had substantial contacts and business relationships throughout the United States, including in Ohio. Moreover, Defendants have substantial contacts and business dealings directly within Ohio by virtue of their distribution, dispensing and sales of prescription opioids.

34. Venue is proper in the Northern District of Ohio pursuant to this Court's Case Management Order One ¶ 6(a), *In Re: National Prescription Opiate Litigation*, No. 1:17-CV-2804 (N.D. Ohio, Apr. 11, 2018), ECF No. 232, allowing for direct filing into the multidistrict litigation proceedings.[9]

35. The Northern District of Illinois would also be a proper jurisdiction and venue for remand or trial of this action. Plaintiff reserves the right to move for transfer at the conclusion of pretrial proceedings.

36. The Northern District of Illinois has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq*. The Northern District of Illinois has supplemental

[9] In accordance with Case Management Order One, Plaintiff does not concede that Ohio law applies by directly filing in this MDL proceeding.

jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy.

37. The Northern District of Illinois has personal jurisdiction over Defendants. Defendants have engaged in conduct and activities over a long time, systematically, individually, jointly and severally, that have caused the damages of Plaintiff, all of which form the bases of the causes of action in this Complaint as against Defendants. Defendants have committed multiple torts and breaches throughout the United States, including in Chicago, Illinois, repeatedly and systematically. Defendants, for a long time, repeatedly and systematically, have had substantial contacts and business relationships throughout the United States, including in Chicago, Illinois. These include consensual relationships and contracts performed within and in each community in which Plaintiff's hospitals are located, some or all of which form the basis of the causes of action in this Complaint as against Defendants. Moreover, Defendants have substantial contacts and business dealings directly within Chicago, Illinois by virtue of their distribution, dispensing and sales of prescription opioids.

38. Venue is proper in the Northern District of Illinois pursuant to 28 U.S.C. § 1391(b)(2) in that a substantial part of the events giving rise to the claims occurred in the Northern District of Illinois.

39. All causes of action herein relate to Defendants' wrongful actions, conduct and omissions throughout the United States, including in Ohio and Illinois, committed against Plaintiff, and the consequences and damages related to said wrongful actions, conduct and omissions.

IV. FACTUAL BACKGROUND

A. THE OPIOID EPIDEMIC

40. Opioids or opiates include "[a]ny of various sedative narcotics containing opium or one or more of its natural or synthetic derivatives."[10] The Controlled Substances Act ("CSA") defines "opiate" or "opioid" as "any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining ability."[11]

41. The United States Food and Drug Administration's website describes this class of drugs as follows: "Prescription opioids are powerful pain-reducing medications that include prescription oxycodone, hydrocodone, and morphine, among others, and have both benefits as well as potentially serious risks."[12] These medications can help manage pain when prescribed for the right condition and when used properly. But when misused or abused, they can cause serious harm, including addiction, overdose, and death.

42. Prescription opioids with the highest potential for addiction are categorized under Schedule II of the Controlled Substances Act.[13] They include non-synthetic derivatives of the opium poppy (such as codeine and morphine, which are also called "opiates"), partially synthetic derivatives (such as hydrocodone and oxycodone), or fully synthetic derivatives (such as fentanyl and methadone).

[10] Opioids, The American Heritage Dictionary (3d. ed. 1992).
[11] 21 U.S.C. § 802(18). The Controlled Substances Act is contained in 21 U.S.C. 801 *et seq.*
[12] *Opioid Medications*, U.S. Food and Drug Administration, https://www.fda.gov/Drugs/DrugSafety/Informationby DrugClass/ucm337066.htm (last accessed Apr. 24, 2019).
[13] U.S. Dep't of Justice, Drug Enforcement Administration, Diversion Control Division, *Controlled Substance Schedules*, https://www.deadiversion.usdoj.gov/schedules/#define.

43. The past two decades have been characterized by increased abuse and diversion of prescription drugs, including opioid medications, in the United States.[14]

44. Prescription opioids have now become widespread. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[15]

45. By 2011, the U.S. Department of Health and Human Resources, Centers for Disease Control and Prevention, ("CDC") declared prescription painkiller overdoses at epidemic levels. Specifically, the CDC reported that the death toll from overdoses of prescription painkillers has more than tripled in the past decade and more than 40 people die every day from overdoses involving narcotic pain relievers like hydrocodone (Vicodin), methadone, oxycodone (OxyContin), and oxymorphone (Opana).[16]

46. The increased use of prescription painkillers for nonmedical reasons, along with growing sales, has contributed to a large number of overdoses and deaths. In 2010, 1 in every 20 people in the United States age 12 and older – a total of 12 million people – reported using prescription painkillers non-medically according to the National Survey on Drug Use and Health.[17]

47. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is unacceptable. The rate of death from opioid overdose has quadrupled during the past 15 years in the United States. Nonfatal opioid overdoses that

[14] *See* Richard C. Dart, *et. al*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).
[15] Katherine M. Keyes, et al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, 104 Am. J. Pub. Health 52 (2014).
[16] *See* U.S. Dep't of Health and Human Services, Centers for Disease Control and Prevention, Press Release, *Prescription Painkiller Overdoses at Epidemic Levels* (Nov. 1, 2011), https://www.cdc.gov/vitalsigns/painkilleroverdoses/index.html.
[17] *See id.*

require medical care in a hospital or emergency department have increased by a factor of six in the past 15 years.[18]

48. In 2016, drug overdoses killed roughly 64,000 people in the United States, an increase of more than 22 percent over the 52,404 drug deaths recorded the previous year.[19]

49. The CDC released a report analyzing opioid-related hospital emergency department data between July 2016 and September 2017 and finding that nearly two thirds (66.4%) of drug overdose deaths in 2016 involved prescription opioids, illicit opioids, or both, an increase of 27.7% from 2015.[20]

50. There are over 5,200 hospitals in the United States and nearly all have been impacted by the increased abuse and diversion of opioids in the United States.

51. The literature reflects a near doubling of intensive care unit ("ICU") overdose deaths nationally between 2009 and 2015.[21] Renal failure was the leading cause, which is associated with high treatment costs due to dialysis costs and medication management. The cost of an opioid-related ICU admission rose greatly, with larger numbers of patients requiring renal transplant therapy. These patients are sicker at presentation and their expenses are rapidly increasing.

[18] *See* Volkow & McLellan, *supra* note 2.
[19] *See* U.S. Dep't of Health and Human Services, Centers for Disease Control and Prevention, *Provisional Counts of Drug Overdose Deaths* (August 8, 2016), https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf.
[20] *See* Vivolo-Kantot, et al., *Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses – United States, July 2016-September 2017*, Ctrs for Disease Control and Prevention, U.S. Dep't of Human and Health Servs. (Mar. 9, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6709e1.htm.
[21] Jennifer P. Stevens, et al., *The Critical Care of Opioid Overdoses in the United States*, 14(12) Ann. Am. Thorac Soc. 1803-09 (Dec. 2017).

52. Moreover, the CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to be addicted to heroin.[22]

53. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk factor for heroin use.[23]

54. Across the nation, hospitals are struggling with a pernicious, ever-expanding epidemic of opioid addiction and abuse. Every day, more than 90 Americans lose their lives after overdosing on opioids.[24]

55. The National Institute on Drug Abuse identifies misuse and addiction to opioids as "a serious national crisis that affects public health as well as social and economic welfare."[25] The economic burden of prescription opioid misuse alone is $78.5 billion a year, including costs of healthcare, lost productivity, addiction treatment, and criminal justice expenditures.[26]

56. In 2016, the President of the United States declared an opioid and heroin epidemic.[27]

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[22] *See* U.S. Dep't of Health and Human Services, Centers for Disease Control and Prevention, *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/index.html.
[23] *See* Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016).
[24] NIH, National Institute on Drug Abuse, *Opioid Crisis* n.1 [hereinafter "Opioid Crisis, NIH"] (citing RA Rudd, et al., *Increases in Drug and Opioid-Involved Overdose Deaths - United States, 2010-2015*, 65 Morbidity and Mortality Weekly Report 50-51 (2016), https://www.drugabuse.gov/drugs- abuse/opioids/opioid-crisis) (last visited Sept. 19, 2017).
[25] Opioid Crisis, NIH, *supra* note 24.
[26] CS Florence, et al., *The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States*, 2013, 54 Med Care 901-06 (2016).
[27] *See* Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").

57. The epidemic of prescription pain medical and heroin deaths is devastating families and communities across the country.[28] Meanwhile, the manufacturers and distributors of prescription opioids extract billions of dollars of revenue from the addicted American public while billions of dollars of injury are caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic.

58. The prescription opioid manufacturers and distributors, including the Defendants, have continued their wrongful, intentional, and unlawful conduct, despite their knowledge that such conduct is causing and/or contributing to the national, state, and local opioid epidemic.

B. THE ILLINOIS OPIOID EPIDEMIC

59. Chicago, Illinois has been especially ravaged by the national opioid crisis.

60. Data is maintained by the Agency for Healthcare Research and Quality for 2008 through 2016 regarding in-patient hospital stays that are attributable to opioid-related complications. The annual rate of such stays per 100,000 population has continued to increase.[29]

61. Between 2010 and 2015, the rate of opioid-overdose-related emergency department visits in Loretto Hospital of Chicago has dramatically increased.

C. THE IMPACT OF DEFENDANTS' CONDUCT ON LORETTO HOSPITAL OF CHICAGO

62. Loretto Hospital of Chicago is a 177-bed facility staffed with an interdisciplinary team of some of the finest doctors, specialists, and nurses in Chicago. Loretto Hospital of Chicago serves over 33,000 patients per year. Loretto Hospital of Chicago provides:

- Addiction Services through their Addiction Center
- Behavioral Health Services

[28] *See* Presidential Memorandum – Addressing Prescription Drug Abuse and Heroin Use, 2015 Daily Comp. Pres. Doc. 743 (Oct. 21, 2015), https://obamawhitehouse.archives.gov/the-press-office/2015/10/21/presidential-memorandum-addressing-prescription-drug-abuse-and-heroin.

[29] *See* Agency for Healthcare Research & Quality, Healthcare Cost & Utilization Project, *State Inpatient Databases 2008-2016*.

- Cancer Screenings
- Critical Care
- Dental Care
- Emergency Medicine
- Eye Care
- Hearing Services
- In-Patient Mental Health
- Laboratory
- Medical/Surgical
- Nutritional Services
- Orthopedics and Podiatry
- Out-Patient Mental Health
- Pharmacy
- Physical, Occupational and Speech Therapy
- Radiology/Diagnostic Imaging
- Senior Services
- Social Services
- Specialty Services
- Surgical Services

63. Plaintiff Loretto Hospital of Chicago has purchased and continues to purchase and administer opioids marketed, sold and distributed by Defendants.

64. Plaintiff has treated, and continues to treat, numerous patients for opioid-related conditions, including: (1) opioid overdose; (2) opioid addiction; (3) neonatal treatment for babies born opioid-addicted because their mothers were opioid addicts for which treatment is specialized, intensive, complex, and lengthy; and (4) conditions related to opioid use and addiction.

65. Plaintiff has incurred and continues to incur substantial unreimbursed or under-reimbursed charges for its treatment of patients with opioid-related conditions. These patients with opioid-related conditions presented for treatment to Plaintiff's hospitals as a proximate result of the opioid epidemic created and engineered by Defendants. As a result, Plaintiff's monetary losses with respect to these patients were and are foreseeable to Defendants and are the proximate result of Defendants' acts and omissions as identified herein.

66. Plaintiff has also had to incur operational costs in the form of surgical procedures and other care that have been and are more complex and expensive than would otherwise be the case if the patients were not opioid addicts.

67. Additionally, opioid users have presented and continue to present themselves to Plaintiff's hospitals claiming to have illnesses and medical problems, which are actually pretexts for obtaining opioids to satisfy their cravings. Plaintiff has incurred and continues to incur operational costs related to the time and expenses in diagnosing, testing, and otherwise dealing with such "pill seekers" before their true medical status can be determined.

68. The costs incurred by Plaintiffs' hospitals are the direct and proximate result of the opioid epidemic created and engineered by Defendants.

69. Because opioids are very dangerous and highly addictive drugs, it was foreseeable to Defendants that the opioid epidemic would result in a corresponding epidemic of patients with opioid-related conditions going to hospitals for treatment, including Plaintiff's facilities. It was also foreseeable to Defendants that Plaintiff would suffer and continue to suffer substantial monetary losses because of the opioid epidemic, since hospitals are on the front-line of treatment for these patients and must bear the additional costs of treating these patients.

70. Defendants have marketed and continue to market their opiate products directly to Plaintiff and to doctors on staff at Plaintiff's hospitals, and thus Plaintiff was and is a direct customer and victim of the Defendants' false, deceptive, and unfair marketing of opioids described herein.

71. As a direct and proximate result of Defendants' misconduct, Plaintiff has purchased opiates from the Defendants, and used them as they were falsely and deceptively marketed by

Defendants, and suffered damages as a direct and proximate cause of Defendants' acts as described in this Complaint.

72. Plaintiff brings this civil action to recover monetary losses that have been incurred as a direct and proximate result of Defendants' false, deceptive, and unfair marketing of prescription opioids. Such economic damages were foreseeable to Defendants and were sustained because of Defendant' unlawful actions and omissions.

73. Plaintiff brings this suit against manufacturers of prescription opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to hospitals and doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded hospitals and their doctors to purchase and prescribe highly addictive, dangerous opioids.

74. Plaintiff also brings this suit against the wholesale distributors and retailers of these highly addictive drugs. The distributors and manufacturers unlawfully breached their legal duties under federal law to monitor, detect, investigate, and report suspicious orders of prescription opiates which allowed the manufacturers' deceptive advertising to result in sales of their products to hospitals, including Plaintiff's hospitals.

D. THE PHARMACEUTICAL DEFENDANTS FALSELY, DECEPTIVELY, AND UNFAIRLY MARKETED OPIOIDS

1. Pharmaceutical Defendants Have a Duty to Exercise Reasonable Care and Skill in Accordance with Applicable Standards of Conduct.

75. The Pharmaceutical Defendants have a legal duty to not expose Plaintiff to an unreasonable risk of harm.

76. The Pharmaceutical Defendants have a legal duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in manufacturing, advertising, marketing, selling, and/or distributing opioids.

2. Pharmaceutical Defendants Made Multiple Misrepresentations in their Opioid Marketing

77. To establish and exploit the lucrative market of chronic pain patients, each Pharmaceutical Defendant developed a well-funded, sophisticated, and negligent marketing and/or distribution scheme targeted at consumers and medical providers. These Defendants used direct marketing, as well as veiled advertising by seemingly independent third parties to spread misrepresentations about the risks and benefits of long-term opioid use – statements that created the "new" market for prescription opioids, upended the standard medical practice, and benefited other Defendants and opioid manufacturers. These statements were unsupported by and contrary to the scientific evidence and targeted susceptible prescribers and vulnerable patient populations, including those in the communities served by Plaintiff.

78. The Pharmaceutical Defendants spread their false and negligent statements by marketing their branded opioids directly to medical providers and patients. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and negligent statements about the risks and benefits of opioids for the treatment of chronic pain throughout geographic areas and patient demographics of the communities served by Plaintiff.

79. The Pharmaceutical Defendants' direct and branded ads negligently portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website www.opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs, misleadingly implying that the drug would provide long-term pain relief and functional improvement. Purdue ran a series of ads, called "Pain Vignettes," for

OxyContin that featured chronic pain patients and recommended OxyContin for each patient-type. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

80. The Pharmaceutical Defendants also promoted the use of opioids for chronic pain through "detailers" – sophisticated and specially trained sales representatives who visited individual doctors and medical staff, and fomented small-group speaker programs. In 2014, for instance, these Defendants spent almost $200 million on detailing[30] branded opioids to medical providers.

81. The FDA has cited at least one of these Defendants for negligent promotions by its detailers and direct-to-physician marketing. In 2010, an FDA-mandated "Dear Doctor" letter required Actavis to inform doctors that "Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."[31]

82. The Pharmaceutical Defendants invited doctors to participate, for payment and other remuneration, on and in speakers' bureaus and programs paid for by these Defendants. These speaker programs were designed to provide incentives for doctors to prescribe opioids, including recognition and compensation for being selected as speakers.[32] On information and belief, these

[30] Detailing refers to the activity of pharmaceutical sales representatives (reps) when they make calls to physicians and provide them with "details" – approved scientific information, benefits, side effects, or adverse events – related to a drug.
[31] *See* Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").
[32] Art Van Zee, MD, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99 Am. J. Public Health 221-27 (2009).

presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

83. The Pharmaceutical Defendants' detailing to medical providers was highly effective in the national proliferation of prescription opioids. Defendants used sophisticated data mining and intelligence to track and understand the rates of initial prescribing and renewal by individual doctors, allowing specific and individual targeting, customizing, and monitoring of their marketing.[33]

84. The Pharmaceutical Defendants have had unified marketing plans and strategies from state to state, including Illinois. This unified approach ensures that Defendants' messages were and are consistent and effective across all their marketing efforts.[34]

85. The Pharmaceutical Defendants negligently marketed opioids through unbranded advertising that promoted opioid use generally, yet was silent as to a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, but funded, directed, coordinated, edited, and distributed, in part or whole, by these Defendants and their public relations firms and agents.

86. The Pharmaceutical Defendants used putative third-party, unbranded advertising to avoid regulatory scrutiny as such advertising is not submitted to or reviewed by the FDA. These Defendants used third-party, unbranded advertising to create the false appearance that the negligent messages came from an independent and objective source.

87. The Pharmaceutical Defendants collaborated to spread negligent messages about the risks and benefits of long-term opioid therapy.

[33] *See id.*
[34] *See id.*

88. To convince medical providers and patients in Chicago, Illinois and elsewhere that opioids can and should be used to treat chronic pain, these Defendants had to persuade them that long-term opioid use is both safe and helpful. Knowing that they could do so only by conveying negligent misrepresentations to those medical providers and patients about the risks and benefits of long-term opioid use, these Defendants made claims that were not supported by or were contrary to the scientific evidence and which were contradicted by data.[35]

89. To convince medical providers and patients that opioids are safe, the Pharmaceutical Defendants negligently trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (a) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (b) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (c) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to make them today.

90. The Pharmaceutical Defendants negligently claimed that the risk of opioid addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly, and failed to disclose the greater risk of addiction with prolonged use of opioids. Some examples of these negligent misrepresentations by opioid manufacturers are:

[35] M. Von Korff, et al., *Long-Term Opioid Therapy Reconsidered*, 155 Ann. Intern Med. 325-328 (2011).

a. Actavis employed a patient education brochure that negligently claimed opioid addiction is "less likely if you have never had an addiction problem";

b. Cephalon and Purdue sponsored a publication by the American Pain Foundation ("APF") entitled Treatment Options: A Guide for People Living with Pain negligently claiming that addiction is rare and limited to extreme cases of unauthorized doses;[36]

c. Endo sponsored a website, Painknowledge.com, which negligently claimed that "[p]eople who take opioids as prescribed usually do not become addicted";

d. Endo distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain which stated that: "most people do not develop an addiction problem";

e. Janssen distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults[37] which described as "myth" the claim that opioids are addictive;

f. a Janssen website negligently claimed that concerns about opioid addiction are "overestimated";

g. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, [38] which negligently claims that pain is undertreated due to "misconceptions about opioid addiction";

[36] Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician's Guide* 62 (2007); American Pain Foundation, *Treatment Options: A Guide for People Living with Pain*, https://ce4less.com/Tests/Materials/E019Materials.pdf [hereinafter *Treatment Options*].

[37] *Finding Relief Pain Management for Older Adults* (2009), https://docplayer.net/28610911-Finding-relief-pain-management-for-older-adults.html.

[38] American Pain Foundation, *A Policymaker's Guide to Understanding Pain & Its Management* (2011), https://www.documentcloud.org/documents/277603-apf-policymakers-guide [hereinafter *A Policymaker's Guide to Understanding Pain*].

h. Purdue produced a promotional video for OxyContin in 1998 that stated that "the rate of addiction amongst pain patients who are treated by doctors is much less than 1%" and that opioids "do not have serious medical side effects";[39]

i. Abbott sales staff were trained to tell physicians that OxyContin had fewer of the euphoric side effects associated with the shorter-acting painkiller Vicodin, and Abbott's "King of Pain," Jerry Eichhorn, taught his staff of "Royal Crusaders" that OxyContin would "minimiz[e] the risk of dependence" and "lower[] euphoria," when, in fact, he had little knowledge of pharmacology and no basis for these statements.[40]

j. Purdue's unbranded website "Partners Against Pain" stated that it was a "[m]yth" that "[o]pioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids" and that addiction risk "appears to be low when opioids are dosed properly for chronic, non-cancer pain";

k. Mallinckrodt's C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance promoted a book entitled Defeat Chronic Pain Now! which claimed that "[w]hen chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving" and "[o]nly a minority of chronic pain patients who are taking long-term opioids develop tolerance";

[39] *I Got My Life Back*, Purdue Pharma OxyContin Commercial, https://www.youtube.com/watch?v=Er78Dj5hyeI.
[40] David Armstrong, *Secret Trove Reveals Bold 'Crusade' to Make OxyContin a Blockbuster*, STAT (Sept. 22, 2016), https://www.statnews.com/2016/09/22/abbott-oxycontin-crusade/.

l. Janssen's website for Duragesic stated, "Addiction is relatively rare when patients take opioids appropriately," in response to a hypothetical patient's concern that he would "become a drug addict";

m. Depomed's Senior Vice President and Chief Financial Officer, August Moretti, told investors that "[a]lthough not in the label, there's a very low abuse profile and side effect rate" for Nucynta.

n. another Endo website, PainAction.com, stated that "[m]ost chronic pain patients do not become addicted to the opioid medications that are prescribed for them"; and

o. Janssen's unbranded website "Prescribe Responsibly" stated that concerns about addiction were "overestimated" and that "true addiction occurs only in a small percentage of patients."[41]

91. These claims are contrary to scientific evidence, as the FDA and CDC have now conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])."[42] The Guideline points out that "[o]pioid pain medication use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for three (3) months substantially increases risk for opioid use disorder."

92. The FDA further exposed the falsity of the Pharmaceutical Defendants' claims about the low risk of addiction when it announced changes to the labels for certain opioids in 2013 and for other opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse,

[41] Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, PRESCRIBE RESPONSIBLY (July 2, 2015), http://www.prescriberesponsibly.com/articles/opioid-pain-management.

[42] Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain*, https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

93. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder."[43] Endo had claimed on its website, www.opana.com, that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State of New York found no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. This agreement, however, did not extend to the other states in which Plaintiff hospitals are located.

94. The Pharmaceutical Defendants negligently instructed medical providers and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudoaddiction." Defendants negligently claimed that pseudoaddiction was substantiated by scientific evidence. Some

[43] *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No. 15-228, Assurance of Discontinuance Under Executive Law § 63, Subdivision 15, https://www.ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

examples of these negligent claims are: (a) Cephalon and Purdue sponsored Responsible Opioid Prescribing, which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction; (b) Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudo-addiction . . . refers to patient behaviors that may occur when pain is under-treated"; (c) Endo sponsored a National Initiative on Pain Control (NIPC) CME program titled Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia,[44] which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain; (d) Purdue sponsored a negligent CME program entitled Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse in which a narrator notes that because of pseudoaddiction, a doctor should not assume the patient is addicted; and (e) Purdue circulated an unbranded pamphlet entitled Clinical Issues in Opioid Prescribing from in or about 2005 to in or about 2013 that listed "illicit drug use and deception" as evidence of "pseudo-addiction" caused by untreated pain, not true addiction.

95. The 2016 CDC Guideline rejects the concept of pseudoaddiction, explaining that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should reassess "pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[45]

96. The Pharmaceutical Defendants negligently instructed medical providers and patients that addiction risk screening tools, patient agreements, urine drug screens, and similar

[44] National Initiative on Pain Control, *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, http://www.cmeweb.com/gevent_detail.php?event_id=884&start=&sort=&PHPSESSID=c1cd1e6883a281d24662e56abeb67fee.
[45] *Supra* note 42.

strategies were very effective to identify and safely prescribe opioids to even those patients predisposed to addiction. These misrepresentations were reckless because Pharmaceutical Defendants directed them to general practitioners and family doctors who could lack the time and expertise to closely manage higher-risk patients on opioids. Pharmaceutical Defendants' misrepresentations were intended to make medical providers more comfortable in prescribing opioids. Some examples of these negligent claims are: (a) an Endo supplement in the Journal of Family Practice emphasized the effectiveness of screening tools to avoid addictions; (b) Purdue's webinar, Managing Patient's Opioid Use: Balancing the Need and Risk, claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths"; (c) Purdue represented in scientific conferences that "bad apple" patients – and not opioids – were the source of the addiction crisis; (d) Purdue's unbranded website "Partners Against Pain" stated, "Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids"; (e) Cephalon sponsored a continuing medical education ("CME") resentation offered by Medscape in 2003 entitled Pharmacologic Management of Breakthrough or Incident Pain that taught that "[c]linicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse" and "[t]he concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse"; (f) Mallinckrodt's C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance promoted a book entitled Defeat Chronic Pain Now! which asserted as "[t]he bottom line" that "[o]nly rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction" and as "fact[]" that "[i]t is very uncommon for a person

with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain"; and (g) Purdue's COO told members of the United States Congress in 2001 that although there had been "a number of cases" of "overdoses and deaths[, v]irtually all of th[o]se reports involve[d] people who [were] abusing the medication, not patients with legitimate medical needs."

97. The 2016 CDC Guideline exposes the falsity of these misrepresentations, noting that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts – "for improving outcomes related to overdose, addiction, abuse, or misuse."[46] The Guideline emphasizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and now counsels that medical providers "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

98. To underplay the risk and impact of addiction and make medical providers feel more comfortable starting patients on opioids, Pharmaceutical Defendants negligently claimed that opioid dependence can easily be solved by tapering, that opioid withdrawal was not difficult, and that there were no problems in stopping opioids after long-term use.

99. A CME sponsored by Endo entitled Persistent Pain in the Older Adult claimed that withdrawal symptoms could be avoided by tapering a patient's opioid dose by up to 20% for a few days. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation,"[47] without mentioning any known or foreseeable issues.

[46] *Supra* note 42.
[47] *Supra* note 38.

100. Pharmaceutical Defendants negligently minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction[48]– and grossly understated the difficulty of tapering, particularly after long-term opioid use.

101. The Pharmaceutical Defendants negligently claimed that medical providers and patients could increase opioid dosages indefinitely without added risk of addiction and other health consequences, and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, medical providers would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. For example: (a) an Actavis patient brochure stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction"; (b) Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain, claiming that some patients need larger doses of opioids, with "no ceiling dose" for appropriate treatment of severe, chronic pain; [49] (c) an Endo website, painknowledge.com, claimed that opioid dosages may be increased until "you are on the right dose of medication for your pain"; (d) an Endo pamphlet, Understanding Your Pain: Taking Oral Opioid Analgesics, stated "The dose can be increased. . . . You won't 'run out' of pain relief";[50] (e) a

[48] *Supra* note 42.
[49] *Treatment Options*, *supra* note 36.
[50] Margo McCaffery, RN, MS, FAAN & Chris Pasero, RN, MS, FAAN, Endo Pharmaceuticals, *Understanding Your Pain – Taking Oral Opioid Analgesics* (2004), http://www.thblack.com/links/rsd/understand_pain_opioid_analgesics.pdf (accessed November 5, 2018).

Janssen patient education guide, Finding Relief: Pain Management for Older Adults, listed dosage limitations as "disadvantages" of other pain medicines yet omitted any discussion of risks of increased opioid dosages;[51] (f) Purdue's "In the Face of Pain" website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will; (g) Purdue's A Policymaker's Guide to Understanding Pain & Its Management stated that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages;[52] (h) a Purdue CME entitled Overview of Management Options taught that NSAIDs and other drugs, but not opioids, were unsafe at high dosages; (i) Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose; and (j) Purdue advised prescribers that "dose adjustments may be made every 1-2 days" and the "total daily dose can usually be increased by 25% to 50%" without addressing the increased risk of respiratory depression and death from the increased dose.[53]

102. These and other representations were not true, as now confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC states that "there is an increased risk for opioid use disorder, respiratory depression, and death at

[51] *Supra* note 37.
[52] *Supra* note 38.
[53] Purdue Pharma, L.P., *OxyContin Risk Evaluation and Mitigation Strategy*, https://web.archive.org/web/20170215190303/http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf.

higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.[54]

103. The 2016 CDC Guideline reinforces findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events."[55] For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

104. Pharmaceutical Defendants' marketing of the so-called abuse-deterrent properties of some of their opioids created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.[56]

105. Pharmaceutical Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER negligently claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse.[57] The FDA warned in a 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse."[58] Moreover, Endo's own studies, which it failed to disclose, showed that

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[54] *Supra* note 42.

[55] United States Food and Drug Administration, *FDA/CDER Response to Physicians for Responsible Opioid Prescribing Partial Petition Approval and Denial*, https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm363722.htm.

[56] Catherine S. Hwang, et al., *Primary Care Physicians' Knowledge and Attitudes Regarding Prescription Opioid Abuse and Diversion*, 32 The Clinical J. of Pain 279-84 (Apr. 2016), https://journals.lww.com/clinicalpain/Abstract/2016/04000/Primary_Care_Physicians__Knowledge_And_Attitudes.1.aspx.

[57] MPR, *Opana ER in a Crush-Resistant Formulation Available*, https://www.empr.com/news/endo-launches-new-crush-resistant-opana-er-dosage-strengths/article/272185/.

[58] U.S. Food and Drug Administration, *FDA Statement: Original Opana ER Relisting Determination*, http://wayback.archiveit.org/7993/20170722191535/https://www.fda.gov/Drugs/DrugSafety/ucm351357.htm (last visited Nov. 5, 2018).

Opana ER could still be ground and chewed.[59] Further, Purdue sales representatives represented to health care providers and prescribers that its reformulated OxyContin prevented tampering, in that it could not be crushed or snorted, and that it was non-addictive or less addictive than the previous formulation. Similarly, Mallinckrodt advertised that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving"[60] and "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive deterrent ingredients.[61]

106. These numerous, longstanding misrepresentations minimizing the risks of long-term opioid use had their desired effects on medical providers and patients. Pharmaceutical Defendants persuaded them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes plain, there was "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, Defendants negligently and misleadingly touted the benefits of long-term opioid use and negligently and misleadingly suggested that these benefits

[59] U.S. Food and Drug Administration, FDA Advisory Committee Meeting, *OPANA ER Briefing Document* (March 13-14, 2017), https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM545762.pdf.
[60] *Press Release*, Medtronic (Aug. 27, 2012), http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159.
[61] Mallinckrodt, *Responsible Use of Opioid Pain Medications* (Mar. 7, 2014).

were supported by scientific evidence. Not only have Defendants failed to correct these false and negligent claims, they continue to make them today.

107. For example, the Pharmaceutical Defendants negligently claimed that long-term opioid use improved patients' function and quality of life, including the following misrepresentations: (a) an Actavis advertisement claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives; (b) an Endo advertisement claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks, portraying seemingly healthy, unimpaired persons; (c) a Janssen patient education guide Finding Relief: Pain Management for Older Adults stated as "a fact" that "opioids may make it easier for people to live normally" such as sleeping peacefully, working, recreating, having sex, walking, and climbing stairs; (d) Purdue advertisements of OxyContin entitled "Pain Vignettes" implied that OxyContin improves patients' function; (e) Responsible Opioid Prescribing, by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function; (f) Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain, which counseled patients that opioids "give [pain patients] a quality of life we deserve"; (g) Endo's NIPC website painknowledge.com claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse"; (h) Endo CMEs titled Persistent Pain in the Older Patient claimed that chronic opioid therapy had been "shown to reduce pain and improve depressive symptoms and cognitive functioning"; (i) Janssen sponsored, funded, and edited a website, Let's Talk Pain, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function"; (j) Purdue's A Policymaker's Guide to Understanding Pain & Its

Management claimed that "multiple clinical studies" had shown opioids as effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients;[62] (k) Purdue's, Cephalon's, Endo's, and Janssen's sales representatives conveyed the message that opioids will improve patient function; (l) Purdue ran a full-page advertisement for OxyContin in the Journal of the American Medical Association that proclaimed "There Can Be Life With Relief" and depicted a man fly-fishing;[63] and (m) Mallinckrodt's website claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[64]

108. These claims are not supported by the scientific literature. The 2016 CDC Guideline concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely".[65] The CDC reinforced this conclusion throughout its 2016 Guideline:

- "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later. . . ."
- "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."
- "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

109. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[66]

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[62] *Supra* note 38.
[63] Chris Adams, *FDA Orders Purdue Pharma To Pull Its OxyContin Ads*, Wall St. J., Jan. 23, 2003, https://www.wsj.com/articles/SB1043259665976915824.
[64] *Responsible Use*, MALLINCKRODT PHARMS., http://www.mallinckrodt.com/corporate-responsibility/responsible-use (last accessed Apr. 17, 2019).
[65] *Supra* note 42.
[66] *Id.*

110. Pharmaceutical Defendants had been warned about the lack of evidence supporting their claims. For example, in 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[67] Likewise, in 2008, the FDA sent a warning letter to another opioid manufacturer, stating "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

111. The Pharmaceutical Defendants also negligently and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs (nonsteroidal anti-inflammatory drugs), so that medical providers and patients would look to opioids first for the treatment of chronic pain. For example, APF's A Policymaker's Guide to Understanding Pain & Its Management, sponsored by Purdue and Cephalon, warned that risks of NSAIDs increase if "taken for more than a period of months" and (falsely) attributed 10,000 to 20,000 deaths annually to NSAID overdose, with no corresponding warning for opioids.

112. Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC. Indeed, the FDA changed the labels for ER/LA (extended-release/long-acting) opioids in 2013 and IR (immediate-release)opioids in 2016[68] to

[67] U.S. Food and Drug Administration, Inspections, Compliance, Enforcement, and Criminal Investigations, *Warning Letter to Actavis Elizabeth LLC* (Feb. 18, 2010), https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.

[68] U.S. Food and Drug Administration, FDA New Release, *FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death*, (Nov. 5, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." The 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.[69]

113. In addition, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours for patients – a fact that Purdue has known at all relevant times. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experienced it. This not only renders Purdue's promise of 12 hours of relief false and negligent, but it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring dependence.

114. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue negligently promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue's sales representatives continued to tell medical providers that OxyContin lasts a full 12 hours.

[69] *Supra* note 42.

115. Cephalon negligently marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. The FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients.

116. Despite this, Cephalon conducted a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, journal supplements, and detailing by its sales representatives to give medical providers the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example: (a) Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009,[70] instructing medical providers that "clinically, broad classification of pain syndromes as either cancer or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain; (b) Cephalon's sales representatives set up hundreds of speaker programs for medical providers, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and (c) in December 2011, Cephalon widely disseminated a journal supplement entitled *Special Report: An Integrated Risk Evaluation and Mitigation Strategy for*

[70] Pain Medicine News, *Opioid-Based Management of Persistent and Breakthrough Pain* (March 2009), https://www.painmedicinenews.com/Monographs-and-Whitepapers/Article/03-09/Opioid-Based-Management-of-Persistent-and-Breakthrough-Pain/14270.

Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)[71] to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals – that openly promotes Fentora for "multiple causes of pain" and not just cancer pain.

117. Cephalon's negligent marketing gave medical providers and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

118. Depomed also negligently marketed the safety and efficacy of its opioid drugs to physicians. Depomed has, since at least October 2011, engaged in unsafe and/or unapproved marketing of Lazanda and, with the acquisition from Janssen in January 2015, the Nucynta franchise of pharmaceutical products.

119. Depomed negligently marketed Lazanda for non-cancer pain even though it is only indicated for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[72]

120. Upon information and belief, Depomed actively promoted Lazanda to physicians who do not treat cancer patients, instructed sales representatives to promote Lazanda to non-cancer treating physicians, and discouraged sales representatives from marketing the drug to physicians treating cancer patients, even if the sales representatives were successful in gaining these doctors' business.

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[71] Pharmacy Times, *Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*, https://www.pharmacytimes.com/publications/issue/2012/january2012/r514-jan-12-rems.

[72] *See First Fentanyl Nasal Spray Approved for Cancer Breakthrough Pain*, The ASCO Post (July 15, 2011), https://www.ascopost.com/issues/july-15-2011/first-fentanyl-nasal-spray-approved-for-cancer-breakthrough-pain/.

121. Sales representatives were pressured to target pain management physicians and were trained to divert the conversation to the physicians use of other, similar medications if they received any pushback from the physician. For example, sales representatives were trained to respond by saying "well tell me about your patients taking Actiq," and then extol the relative benefits of switching those patients to Lazanda.

122. Depomed negligently marketed the Nucynta franchise of pharmaceutical products for unapproved and unsafe uses. The Nucynta franchise consists of opioids that include Nucynta ER (tapentadol) extended release tablets indicated for the management of pain, including neuropathic pain associated with diabetic peripheral neuropathy, severe enough to require daily, around-the-clock, long-term opioid treatment; Nucynta IR (tapentadol), an immediate release version of tapentadol, for management of moderate to severe acute pain in adults; and Nucynta (tapentadol) oral solution, an approved oral form of tapentadol that has not been commercialized.

123. The FDA-approved labels for Nucynta and Nucynta ER describe the tapentadol molecule as "a substance with a high potential for abuse similar to other opioids including fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, and oxymorphone."[73] Upon information and belief, Depomed promoted Nucynta drugs as a safer alternative to opioids, despite this not being supported by the FDA label.

124. Depomed management knew that the FDA-approved label for Nucynta contained no information about it being safer, more tolerable, less addictive, or less abusive than alternative opioids, and knew they could not market Nucynta this way. In a March 14, 2015 presentation at the ROTH Conference, then-Depomed CEO Schoeneck stated, "The addiction profile is thought to be better. I can't make a claim around that because we don't actually have that in the label." On

[73] *See Nugynta*, Drugs.com, https://www.drugs.com/pro/nucynta.html (last accessed Apr. 30, 2019); *Nugynta ER*, Drugs.com, https://www.drugs.com/pro/nucynta-er.html (last accessed Apr. 30, 2019).

a June 23, 2015 investor call, August Moretti, Depomed's Senior Vice President and Chief Financial Officer, stated that "[a]lthough not in the label, there's a very low abuse profile and side effect rate."

125. Despite this knowledge, upon information and belief, Depomed initiated a marketing push whereby sale representatives targeted physicians, especially family, primary care physicians, and promoted the use of opioids for all manner of pain management, touted the value of Nucynta relative to other opioids on the market and downplayed the drugs' addictive nature.

126. Upon information and belief, Depomed actively targeted primary care physicians with marketing presentations that described Nucynta as a safer, less addictive, less abusive opioid that did not contain the same euphoric feeling as other opioids. Depomed did not have FDA-approval to market Nucynta in this manner and did not have any independent scientific evidence to support these claims.

127. Depomed trained its sales representatives to use these marketing tactics to sell Nucynta, using the same sales team as Janssen had to promote Nucynta, knowing that Janssen was being sued for, among other things, improperly marketing Nucynta.

128. Depomed's negligent marketing gave medical providers and patients the false impression that Nucynta and Nucynta ER were not only safe and effective for treating chronic pain, but were also approved by the FDA for other uses.

3. The Pharmaceutical Defendants Covertly Circulated their Misleading Marketing Messages through Multiple Channels

129. As a part of their negligent marketing scheme, the Pharmaceutical Defendants identified and targeted susceptible prescribers and vulnerable patient populations throughout the

United States. For example, these Defendants focused their negligent marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs.

130. The Pharmaceutical Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and negligent. The FDA and other regulators warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made plain the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.[74]

131. Moreover, at all times relevant to this Complaint, the Pharmaceutical Defendants took steps to avoid detection of and to fraudulently conceal their negligent marketing and unlawful, unfair, and fraudulent conduct. For example, the Pharmaceutical Defendants disguised their own role in the negligent marketing of chronic opioid therapy by funding and working through third parties. These Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Defendants' false and negligent statements about the risks and benefits of long-term opioid use for chronic pain.

132. The Pharmaceutical Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. These

[74] *In the Matter of Purdue Pharma L.P.*, Assurance No.: 15-151, Assurance of Discontinuance Under Executive Law §63, Subdivision 15.

Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with third parties that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Pharmaceutical Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

133. Finally, the Pharmaceutical Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. These Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for these Defendants' negligent messages was not apparent to medical professionals who relied upon them in making treatment decisions.

134. Thus, the Pharmaceutical Defendants successfully concealed from the medical community and patients the existence and scope of Defendants' industry-wide fraud, as well as facts sufficient to arouse suspicion of the claims that Plaintiff now asserts.

135. In summary, the Pharmaceutical Defendants made and/or disseminated deceptive statements regarding material facts, and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids. The Pharmaceutical Defendants' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

136. Defendant Purdue made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic, non-cancer pain;

c. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

d. Distributing brochures to medical providers, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

e. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic, non-cancer pain;

h. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic, non-cancer pain and misrepresented the risks of opioid addiction;

i. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic, non-cancer pain;

j. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic, non-cancer pain and that opioids improve quality of life, while concealing contrary data;

k. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic, non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

l. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic, non-cancer pain;

m. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic, non-cancer pain and misrepresented the risks of opioid addiction in this population;

n. Disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards;

o. Making deceptive statements concerning the use of opioids to treat chronic, non-cancer pain to prescribers through in-person detailing; and

p. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioids, while simultaneously marketing opioids to these medical providers by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

137. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic, non-cancer pain;

c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;

d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

g. Providing needed financial support to pro-opioid pain organizations – including over $5 million to the organization responsible for many of the most egregious

misrepresentations – that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic, non-cancer pain;

h. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic, non-cancer pain and misrepresented the risks of opioid addiction in this population;

i. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic, non-cancer pain;

j. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic, non-cancer pain and that opioids improve quality of life, while concealing contrary data;

k. Directly distributing and assisting in the dissemination of literature that contained deceptive statements concerning the use of opioids to treat chronic, non-cancer pain, including the concept of pseudo-addiction;

l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic, non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

m. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

138. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic, non-cancer pain and that opioids improve quality of life, while concealing contrary data;

c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudo-addiction through internet sites over which Janssen exercised final editorial control and approval;

d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

f. Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic, non-cancer pain;

g. Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic, non-cancer pain and misrepresented the risks of opioid addiction in this population;

h. Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic, non-cancer pain and improve quality of life, while concealing contrary data;

i. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic, non-cancer pain;

j. Directly distributing and assisting in the dissemination of literature written that contained deceptive statements concerning the use of opioids to treat chronic, non-cancer pain, including the concept of pseudo-addiction;

k. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic, non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

l. Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic, non-cancer pain; and

m. Making deceptive statements concerning the use of opioids to treat chronic, non-cancer pain to prescribers through in-person detailing

139. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudo-addiction, even for high-risk patients;

c. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic, non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

d. Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic, non-cancer pain;

e. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic, non-cancer pain;

f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

g. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of medical providers, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

h. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic, non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

i. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

140. Defendant Actavis made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including, but not limited to, the following:

a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;

b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic, non-cancer pain and that opioids improve quality of life;

c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic, non-cancer pain and that opioids improve quality of life while concealing contrary data.

141. Pharmaceutical Defendants successfully deceived medical providers and patients about the risks and benefits of long-term opioid use. Studies reveal that many medical providers and patients were not aware of the actual risks and benefits. Indeed, patients often report that they did not understand they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 did not know opioids were potentially addictive.

142. Pharmaceutical Defendants' negligent marketing scheme caused and continues to cause medical providers throughout the United States to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent these Defendants' negligent marketing scheme, these medical providers would not have prescribed as many opioids.

These Defendants' negligent marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent these Defendants' negligent marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

E. THE DISTRIBUTOR DEFENDANTS FALSELY AND UNLAWFULLY DISTRIBUTED OPIOIDS.

143. The supply chain for prescription opioids begins with the manufacture and packaging of the pills. The manufacturers then transfer the pills to distribution companies, including Defendants Cardinal, McKesson, and AmerisourceBergen, which together account for 85-90% of all revenues from drug distribution in the United States, an estimated $378.4 billion in 2015. The distributors then supply opioids to pharmacies, doctors, and other healthcare providers for dispensing the drugs to patients.

144. Pharmaceutical Defendants and Distributor Defendants share the responsibility for controlling the availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of prescription opioids is broken, and the drugs are transferred from a legitimate channel of distribution or use, to an illegitimate channel of distribution or use. Diversion can occur at any point in the opioid supply chain.

145. For example, at the wholesale level of distribution, diversion occurs whenever distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders of opioids. Suspicious orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served, orders that deviate from a normal pattern, and/or orders of unusual frequency and duration.

146. Diversion occurs through the use of stolen or forged prescriptions at pharmacies, or the sale of opioids without prescriptions, including patients seeking prescription opioids under false pretenses.

147. Opioid diversion occurs in the United States at an alarming rate.[75] In recent years, the number of people who take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.

148. Every year, millions of people misuse and abuse opioid pain relievers in a way that can lead to addiction, neonatal abstinence syndrome, overdose, and death.[76]

149. Within the last 20 years, the abuse of prescription narcotic pain relievers has emerged as a public health crisis in the United States.

150. The dramatic rise in heroin use in recent years is a direct result of prescription opioid diversion. The strongest risk factor for a heroin use disorder is prescription opioid use. In one national study covering the period 2008 to 2010, 77.4% of the participants reported using prescription opioids before initiating heroin use. Another study revealed that 75% of those who began their opioid abuse in the 2000s started with prescription opioids.[77] The CDC has reported that people who are dependent on prescription opioid painkillers are 40 times more likely to become dependent on heroin.[78]

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[75] James A. Inciardi, et al., *The Diversion of Prescription Opioid Analgesics*, http://cicero.wustl.edu/skip/publications/partner_pubs/8%20%20The%20Diversion%20of%20Prescription%20Opioid%20Analgesics.pdf.

[76] *See* Rebecca Ahrnsbrak, et al., *Key Substance Use and Mental Health Indicators in the United States: Results from the 2016 National Survey on Drug Use and Health. Center for Behavioral Health Statistics and Quality*, Substance Abuse & Mental Health Srvs Admin. 20 (Sept. 2017), https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.pdf).

[77] TJ Cicero, et al., *The Changing Face of Heroin Use in the United States A Retrospective Analysis of the Past 50 Years*, 71 JAMA Psychiatry 821-26 (2014), https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575.

[78] Centers for Disease Control and Prevention, Press Release, *New Research Reveals the Trends and Risk Factors Behind America's Growing Heroin Epidemic*, https://www.cdc.gov/media/releases/2015/p0707-heroin-epidemic.html.

151. The drug distribution industry is supposed to serve as a "check" in the drug delivery system, by securing and monitoring opioids at every step of the stream of commerce, protecting them from theft and misuse, and refusing to fulfill suspicious or unusual orders. Defendants woefully failed in this duty, instead consciously ignoring known or knowable problems and data in their supply chains.

1. Distributor Defendants Have a Duty to Monitor the Supply of Opioids and Avoid Diversion.

152. Distributor Defendants owe a duty under federal and state law to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids as well as those orders that the Distributor Defendants know or should have known are likely to be diverted.

153. Distributor Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

154. In addition to having common law duties, the Distributor Defendants are governed by the statutory requirements of the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq.* and its implementing regulations.[79] These requirements were enacted to protect society from the harms of drug diversion. The Distributor Defendants' violations of these requirements show that they failed to meet the relevant standard of conduct that society expects from them. The Distributor Defendants' repeated, unabashed, and prolific violations of these requirements show that they have acted in total reckless disregard.

[79] Controlled Substances Act, 21 U.S.C. § 801 *et seq*., https://www.deadiversion.usdoj.gov/21cfr/21usc/822.htm.

155. The CSA acts as a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the patient or ultimate user. Every person or entity that manufactures, distributes, or dispenses opioids must obtain a "registration" with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA, otherwise controlled substances move from the legal to the illicit marketplace, and there is enormous potential for harm to the public.

156. All opioid distributors are required to maintain effective controls against opioid diversion. They are also required to create and use a system to identify and report downstream suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.[80]

157. To prevent unauthorized users from obtaining opioids, the CSA creates a distribution monitoring system for controlled substances, including registration and tracking requirements imposed upon anyone authorized to handle controlled substances. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from point of manufacture through commercial distribution channels to point of sale. ARCOS accumulates data on distributors' controlled substances, acquisition transactions, and distribution transactions, which are then summarized into reports used by the DEA to identify any diversion of

[80] Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, 21 CFR §1301.74, https://www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_74.htm.

controlled substances into illicit channels of distribution.[81] Each person or entity that is registered to distribute ARCOS-reportable controlled substances must report acquisition and distribution transactions to the DEA.[82]

158. Acquisition and distribution transaction reports must provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies) for each ARCOS-reportable controlled substance. 21 U.S.C. § 827(d) (l); 21 C.F.R. §§ 1304.33(e), (d). Inventory that has been lost or stolen must also be reported separately to the DEA within one business day of discovery of such loss or theft.

159. In addition to filing acquisition/distribution transaction reports, each registrant is required to maintain a complete, accurate, and current record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. 21 U.S.C. §§ 827(a)(3), 1304.2l(a), 1304.22(b). It is unlawful for any person to negligently fail to abide by the recordkeeping and reporting requirements.

160. To maintain registration, distributors must also maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. When determining if a distributor has provided effective controls, the DEA refers to the security requirements set forth in §§ 130 1.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. 21 CFR § 1301.71.

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[81] Drug Enforcement Administration ARCOS, *What is ARCOS and What Does It Do?*, https://www.deadiversion.usdoj.gov/arcos/index.html.

[82] Drug Enforcement Administration, *ARCOS Registrant Handbook*, https://www.deadiversion.usdoj.gov/arcos/index.html; *id.* at § 2.0 - Reporting Requirements.

161. To combat the problem of opioid diversion, the DEA has provided guidance to distributors on the requirements of suspicious order reporting in numerous venues, publications, documents, and final agency actions. Since 2006, the DEA has conducted one-on-one briefings with distributors regarding their downstream customer sales, due diligence responsibilities, and legal and regulatory responsibilities (including the responsibility to know their customers and report suspicious orders to the DEA).[83] The DEA provides distributors with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled versus non-controlled purchases. The distributors are given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA emphasizes the "red flags" distributors should look for to identify potential diversion.

162. Since 2007, the DEA has hosted no less than five conferences to provide opioid distributors with updated information about diversion trends. The Distributor Defendants each attended at least one of these conferences, which allowed for questions and discussions. The DEA has participated in numerous meetings and events with the legacy Healthcare Distribution Management Association ("HDMA"), now known as the Healthcare Distribution Alliance ("HDA"), an industry trade association for wholesalers and distributors.[84] DEA representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances.

[83] U.S. Drug Enforcement Administration, *Regulatory Section DEA Headquarters ODG*, https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/2010/llevin.pdf.
[84] U.S. Drug Enforcement Administration, *Meetings and Events*, https://www.deadiversion.usdoj.gov/mtgs/index.html.

163. On September 27, 2006 and December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors, including the Distributor Defendants, providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion.

164. The September 27, 2006 letter reminded registrants, including the Distributor Defendants, that they were required by law to exercise due diligence to avoid filling orders that could be diverted into the illicit market. The DEA explained that as part of the legal obligation to maintain effective controls against diversion, the distributor was required to exercise due care in confirming the legitimacy of each and every order prior to filling. It also described circumstances that could be indicative of diversion, including ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; disproportionate ratio of ordering controlled substances versus non-controlled prescription drugs; ordering excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors. The letter went on to describe what questions should be answered by a customer when attempting to make a determination if the order is indeed suspicious.

165. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants, including each of the Distributor Defendants, providing guidance and reinforcing the legal requirements outlined in the September 2006 correspondence. The letter reminded registrants that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants that they must perform an independent analysis of a suspicious

order prior to the sale to determine if the controlled substances would likely be diverted, and that filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility. Finally, the letter directed the registrant community to review a recent DEA action that addressed criteria in determining suspicious orders and their obligation to maintain effective controls against diversion.

166. The HDMA, Distributor Defendants' own industry group, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," emphasizing the critical role of each member of the supply chain in distributing controlled substances.

167. These industry guidelines stated: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

168. For years, the Distributor Defendants have known of the problems and consequences of opioid diversion in the supply chain, and have committed repeated violations of the laws and regulations of the United States as cited above consequently making them liable under the law.

169. Opioid distributors have admitted to the magnitude of the problem and their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

170. For example, a Cardinal executive claimed that Cardinal uses "advanced analytics" to monitor its supply chain. He further extolled that Cardinal was being "as effective and efficient

as possible in constantly monitoring, identifying, and eliminating any *outside* criminal activity."[85] This statement is at odds with the company's sales volumes and history of violations.

171. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our Country."[86]

172. H.D. Smith has stated publicly that it "operates with stringent protection for our nation's healthcare supply chain. The company works with its upstream manufacturing and downstream pharmacy partners to guard the integrity of the supply chain, and to improve patient outcomes."[87]

173. These assurances of identifying and eliminating criminal activity and curbing the opioid epidemic create a duty for the Distributor Defendants to take reasonable measures to do just that.

174. In addition to the obligations imposed by law, through their own words, representations, and actions, the Distributor Defendants have voluntarily undertaken a duty to protect the public at large against diversion from their supply chains, and to curb the opioid epidemic. In this voluntary undertaking, the Distributor Defendants have negligently failed.

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[85] Lenny Bernstein, et al., *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job,"* Wash. Post (Oct. 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.9612d888e603 (emphasis added).

[86] Scott Higham, et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html.

[87] Lindsey Bever, *A town of 3,200 was flooded with nearly 21 million pain pills as addiction crisis worsened, lawmakers say*, WASH. POST (Jan. 31, 2018), https://www.washingtonpost.com/news/to-your-health/wp/2018/01/31/a-town-of-3200-was-flooded-with-21-million-pain-pills-as-addiction-crisis-worsened-lawmakers-say/?noredirect=on&utm_term=.43aa14f9b106.

2. Distributor Defendants Disregarded their Duties and Allowed Diversion to Occur.

175. Distributor Defendants have knowingly or negligently allowed diversion. Their wrongful conduct and inaction has resulted in numerous civil fines and other penalties recovered by state and federal agencies, including actions by the DEA related to violations of the Controlled Substances Act.

176. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. In December 2016, a Department of Justice press release announced a multi-million dollar settlement with Cardinal for violations of the Controlled Substances Act.[88] In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to certain pharmacies.

177. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a $13.25 million civil fine. McKesson also was supposed to implement tougher controls regarding opioid diversion. However, McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer. The DEA and DOJ began investigating

[88] U.S. Dep't of Justice, Press Release, *United States Reaches $34 Million Settlement with Cardinal Health for Civil Penalties under the Controlled Substances Act* (Dec. 23, 2016), https://www.justice.gov/usao-wdwa/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under-0.

McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson admitted to violating the CSA in a Form-8-K announcing a settlement with the DEA and DOJ.[89] In early 2017, it was reported that McKesson agreed to pay a $150 million civil penalty to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.[90]

178. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels. AmerisourceBergen reported that the U.S. Department of Justice subpoenaed AmerisourceBergen in 2012 for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes." [91] AmerisourceBergen received another subpoena in July 2017 relating to AmerisourceBergen's programs to control diversion of its controlled substances during the time period since 2013. AmerisourceBergen continued to receive several substantially similar subpoenas over the next year, as well.

179. Data provided to the U.S. House of Representatives Committee on Energy and Commerce showed that, between 2007 and 2008, H. D. Smith provided two pharmacies in Williamson, West Virginia, a town with a population of 3,191, a combined total of nearly 5

[89] McKesson, *McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims* (Jan. 17, 2017), https://www.mckesson.com/about-mckesson/newsroom/press-releases/2017/mckesson-finalizes-settlement-with-doj-and-dea-to-resolve-past-claims/.
[90] U.S. Dep't of Justice, Press Release (Jan. 17, 2017), https://www.justice.gov/usao-ma/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.
[91] AmerisourceBergen Form 10-Q for Period Ending 6/30/18, at 16, https://seekingalpha.com/filing/4120204.

million hydrocodone and oxycodone pills, an amount sufficient to provide approximately 1,565 hydrocodone and oxycodone pills to every man, woman, and child in Williamson.[92]

180. According to press reports, H. D. Smith distributed approximately 13.7 million hydrocodone and 4.4 million oxycodone pills to West Virginia between 2007 and 2012. Press accounts further indicate that H.D. Smith did not submit any suspicious order reports to the state of West Virginia for at least a decade.[93]

181. On November 23, 2015, the DEA issued an Order to Show Cause to begin the process of revoking Miami-Luken's Certificate of DEA Registration.[94] In its revocation proceeding, the DEA has alleged that Miami-Luken failed to maintain effective controls against diversion of controlled substances and that the company failed to operate a system to disclose suspicious orders of controlled substances when it shipped controlled substances, particularly oxycodone and hydrocodone, to customers in southern Ohio, eastern Kentucky, and southern West Virginia.

182. In early 2016, Miami-Luken agreed to pay the state of West Virginia $2.5 million to resolve allegations that the company knowingly shipped opioids to West Virginia pharmacies without exercising sufficient monitoring or control.[95]

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[92] *Supra* note 87.

[93] *See, e.g.*, Courtney Hessler, *Answers sought on delivery of pills*, THE HERALD-DISPATCH (Feb. 4, 2018), https://www.herald-dispatch.com/news/answers-sought-on-delivery-of-pills/article_fabd35cb-ad5a-5e54-a524-6f766a072721.html.

[94] *See, e.g.*, Eric Eyre, *Congressional opioid investigation targets drug wholesaler Miami-Luken*, Gazette-Mail (Sept. 25, 2017), https://www.wvgazettemail.com/news/health/congressional-opioid-investigation-targets-drug-wholesaler-miami-luken/article_cafddd6d-a31e-540b-941f-5a23a7cc4ae7.html.

[95] *Settlement reached with drug wholesaler*, THE HERALD-DISPATCH (Feb. 4, 2016), https://www.herald-dispatch.com/news/settlement-reached-with-drug-wholesaler/article_e73c8ed5-9b2b-5319-9934-e55a54fb46e0.html https://www.herald-dispatch.com/news/settlement-reached-with-drug-wholesaler/article_e73c8ed5-9b2b-5319-9934-e55a54fb46e0.html.

183. Relying upon state laws and regulation, various state boards of pharmacy have directly disciplined the wholesale distributors of prescription opioids for failure to prevent diversion, a duty recognized under state laws and regulations.

184. Distributor Defendants have the ability and owe the duty to prevent opioid diversion, which presented a known or foreseeable risk of damage to Plaintiff.

185. Distributor Defendants have supplied massive quantities of prescription opioids throughout the United States with the actual or constructive knowledge that the opioids were ultimately being consumed for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but the Distributor Defendants negligently or knowingly failed to do so.

186. Each Distributor Defendant knew or should have known that the amount of the opioids that it allowed to flow into communities throughout the United States was far in excess of what could be consumed for medically-necessary purposes in the relevant communities (especially given that each Distributor Defendant knew it was not the only opioid distributor servicing those communities).

187. Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at large purchases of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers; providing information to pharmacies and retailers about opioid diversion; and in

general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies.

188. On information and belief, the Distributor Defendants made little to no effort to visit pharmacies to perform due diligence inspections to ensure that the controlled substances the Distributor Defendants had furnished were not being diverted to illegal uses.

189. On information and belief, the compensation the Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

190. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding consumer markets in the geographic area served by Plaintiff's hospitals with highly-addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

191. Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

192. Distributor Defendants knew or should have known that a substantial amount of the opioids being dispensed were being dispensed based on invalid or suspicious prescriptions. It is foreseeable that filling suspicious orders for opioids will cause harm, including economic harm to Plaintiff.

193. Distributor Defendants were aware of widespread prescription opioid abuse of persons who would become patients, but they nevertheless persisted in a pattern of distributing

commonly abused and diverted opioids in geographic areas – and in such quantities, and with such frequency – in such a way that shows that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

194. Distributor Defendants failed to report "suspicious orders," or orders which the Distributor Defendants knew were likely to be diverted, to the federal authorities, including the DEA.

195. If any of the Distributor Defendants adhered to effective controls to guard against diversion, Plaintiff would have avoided significant damages.

196. Distributor Defendants made substantial profits over the years based on the diversion of opioids.[96] Their participation and cooperation in a common enterprise has foreseeably caused damages to Plaintiff. The Distributor Defendants knew full well that Plaintiff would be unjustly forced to bear economic costs associated with diversion.

197. Distributor Defendants' intentional distribution of excessive amounts of prescription opioids to communities showed an intentional or reckless disregard for individuals and, in turn, Plaintiff. Their conduct poses a continuing economic threat to the communities that must deal with ongoing medical needs of those addicted to opioids.

F. THE PHARMACEUTICAL DEFENDANTS FALSELY REPRESENTED THAT THEY HAD FULFILLED THEIR DUTIES TO MONITOR THE SUPPLY OF OPIOIDS AND AVOID DIVERSION.

198. The same legal duties to prevent diversion, and to monitor, report, and prevent suspicious orders of prescription opioids that were incumbent upon the Distributor Defendants were also legally required of the Pharmaceutical Defendants under federal law.

[96] Brian Alexander, The Atlantic, *When a Company Is Making Money From the Opioid Crisis* (Sept. 6, 2017), https://www.theatlantic.com/business/archive/2017/09/opioid-crisis-responsibility-profits/538938/.

199. Like the Distributor Defendants, the Pharmaceutical Defendants were required to register with the DEA to manufacture schedule II controlled substances, including prescription opioids.

200. Additionally, as "registrants" under Section 823, the Pharmaceutical Defendants were also required to monitor, report, and prevent suspicious orders of controlled substances. The Pharmaceutical Defendants had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. Pharmaceutical Defendants engaged in the practice of paying "chargebacks" to opioid distributors.[97] A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer's product at a price below a specified rate. After a distributor sells a manufacturer's product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume, and the pharmacy to which it sold the product. Thus, the Pharmaceutical Defendants knew – just as the Distributor Defendants knew – the volume, frequency, and pattern of opioid orders being placed and filled. The Pharmaceutical Defendants built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

201. Federal statutes and regulations are plain: just like opioid distributors, opioid manufacturers are required to "design and operate a system to disclose . . . suspicious orders of controlled substances" and to maintain "effective controls against diversion."[98]

202. The application of these laws to manufacturers, including the Pharmaceutical Defendants, was confirmed recently by the Department of Justice when it imposed fines against

[97] Lenny Bernstein & Scott Higham, *The Government's Struggle to Hold Opioid Manufacturers Accountable*, Wash. Post. (Apr. 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?noredirect=on&utm_term=.a74f05025164.
[98] *Supra* note 75.

Mallinckrodt for $35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. [99]

203. The DEA targeted Mallinckrodt in 2011 about its failure to report suspicious orders of pills, as many as 500 million of which ended up in Florida between 2008 and 2012. Federal prosecutors summarized the case by saying that everyone at Mallinckrodt knew what was going on but did not think they had a duty to report it.[100]

204. In the press release accompanying the settlement, the Department of Justice stated that Mallinckrodt did not meet its obligations to detect and notify the DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. The DOJ went on to state that these suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone, that Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street, and that manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands.[101]

205. The same duties imposed by federal law on Mallinckrodt were imposed upon all Pharmaceutical Defendants.

206. Purdue unlawfully and unfairly failed to report or address illicit and unlawful dispersing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue

[99] U.S. Dep't of Justice, Press Release, *Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations* (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.
[100] Bernstein & Higham, *supra* note 97.
[101] Press Release, *supra* note 99.

is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs.[102] Likewise, despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

207. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.[103]

208. Pharmaceutical Defendants failed to monitor, report, and halt suspicious orders of opioids as required by federal law. The Pharmaceutical Defendants' failures to monitor, report, and halt suspicious orders of opioids were unlawful.

209. Pharmaceutical Defendants have misrepresented their compliance with federal law.

[102] Harriett Ryan, et al., *A Times Investigation: More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, Los Angeles Times, http://www.latimes.com/projects/la-me-oxycontin-part2/.
[103] *Supra* note 41.

210. Pharmaceutical Defendants' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids throughout the United States.

G. DEFENDANTS' UNLAWFUL CONDUCT AND BREACHES OF LEGAL DUTIES CAUSED PLAINTIFF SUBSTANTIAL DAMAGES.

211. As the Pharmaceutical Defendants' efforts to expand the market for opioids increased, so have the rates of prescription and sale of their products – and the rates of opioid-related substance abuse, hospitalization, and death. The Distributor Defendants have continued to unlawfully ship these massive quantities of opioids into communities served by Plaintiff, fueling the epidemic.

212. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[104]

213. Opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose deaths and addictions.[105]

214. As shown above, the opioid epidemic has escalated with devastating effects. Substantial opiate-related substance abuse, hospitalization and death mirrors Defendants' increased distribution of opiates.

215. Because of the well-established relationship between the use of prescription opiates and the use of non-prescription opioids, like heroin,[106] the massive distribution of opioids to the geographic areas served by Plaintiff and areas from which such opioids are being diverted into the

[104] *See* Richard C. Dart, et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).
[105] *See* Centers for Disease Control and Prevention, Press Release, *Prescription Painkiller Overdoses at Epidemic Levels* (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html; Volkow & McLellan, *supra* note 2; Califf, et al., *supra* note 3.
[106] *Supra* note **Error! Bookmark not defined.**.

geographic areas served by Plaintiff, has caused the Defendant-caused opioid epidemic to include heroin addiction, abuse, and death.

216. Defendants repeatedly and purposefully breached their duties under state and federal law, and such breaches are direct and proximate causes of, and/or substantial factors leading to, the widespread diversion of prescription opioids for nonmedical purposes into the geographic areas served by Plaintiff.

217. The unlawful diversion of prescription opioids is a direct and proximate cause of, and/or substantial factor leading to, the opioid epidemic, prescription opioid abuse, addiction, morbidity and mortality in the geographic areas serviced by Plaintiff. This diversion and the epidemic are direct causes of foreseeable harms incurred by Plaintiff.

218. The cost of an opioid-related intensive care unit ("ICU") admission rose from an average of $58,517 to $92,408 between 2009 and 2015.[107] Critically ill overdose patients required renal transplant therapy 37% more often in 2015 than 2009. These patients are sicker at presentation and their expenses are rapidly increasing. The literature reflects an increase of 34% of ICU overdose deaths nationally between 2009 and 2015. Renal failure was the leading cause, the treatment of which is very expensive due to dialysis costs and medication management.

219. Plaintiff incurs operational costs, including costs consisting of expending time and incurring expenses, in diagnosing, testing, and otherwise treating these patients.

220. Plaintiff also incurs operational costs in the form of surgical procedures that are more complex and expensive than would otherwise be the case if the patients were not opioid addicts, which complicates surgical procedures and requires special protective measures.

[107] Jennifer P. Stevens, et al., *The Critical Care of Opioid Overdoses in the United States*, 14 Ann. Am. Thorac Soc. 1803-09 (Dec. 2017).

221. The unreimbursed losses sustained by a hospital can approach $100,000 per non-payer (self-pay) patient. The $100,000 estimate can climb considerably higher for patients staying longer than average due to aspiration pneumonia, septic shock, rhabdomyolysis, and anoxic brain injury. These complications are on the rise because the overdose cases have comorbidity on board at presentation and more individuals are being saved before arriving at the hospital due to expansion of Narcan availability and training. In addition to losses associated with non-payer patients, Plaintiffs also suffered under-reimbursed losses for patients that presented with insurance.

222. These patients' opioid conditions are the direct and proximate result of the opioid epidemic created and engineered by Defendants.

223. Defendants' intentional and/or unlawful conduct resulted in direct and foreseeable, past and continuing, economic damages for which Plaintiff seeks relief, as alleged herein.

224. The economic damages from unreimbursed care are exclusively borne by Plaintiff and no other entity or individual has standing to seek recovery of the unreimbursed care costs.

225. Plaintiff seeks economic damages from the Defendants as reimbursement for the unrecovered and unreimbursed costs, as well as increased operations costs associated with treating patients injured by Defendants' conduct.

226. Plaintiff also seeks injunctive relief and resources to address future harm in order to prevent new cases of opioid addiction, identify early opioid-addicted individuals, and ensure access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.[108]

[108] *See* Johns Hopkins Bloomberg School of Public Health, *The Prescription Opioid Epidemic: An Evidence-Based Approach* (G. Caleb Alexander, et al. eds., 2015), http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/research/prescription-opioids/JHSPH_OPIOID_EPIDEMIC_REPORT.pdf.

227. These community-based problems require community-based solutions that have been limited by "budgetary constraints at the state and Federal levels."[109]

228. Having profited enormously through the aggressive sale, misleading promotion, and irresponsible distribution of opiates, Defendants should be required to take responsibility for the financial burdens their conduct has inflicted upon Plaintiff.

H. STATUTES OF LIMITATIONS ARE TOLLED AND DEFENDANTS ARE ESTOPPED FROM ASSERTING STATUTES OF LIMITATIONS AS DEFENSES.

1. Continuing Conduct.

229. Plaintiff contends it continues to suffer harm from the unlawful actions by the Defendants.

230. The continued tortious and unlawful conduct by the Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by Defendants has not ceased. The conduct causing the damages remains unabated.

231. Defendants have a longstanding and demonstrable policy of misrepresentations and omissions regarding the risks of opioids, Defendants' practices in promoting and marketing opioids, and Defendants' role in allowing diversion of opioids to occur.

2. Equitable Estoppel.

232. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including Plaintiff, that they were undertaking efforts to comply

[109] *See* Office of Nat'l Drug Control Policy, Exec. Office of the President, *Epidemic: Responding to America's Prescription Drug Abuse Crisis* (2011), https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf.

with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including Plaintiff, that they were working to curb the opioid epidemic.[110]

233. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[111]

234. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Distributor Defendants, through HDMA and the National Association of Chain Drug Stores ("NACDS"), filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[112]

- "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."
- "DEA regulations that have been in place for more than 40 years require distributors to *report* suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)."
- "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."
- "A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy."

[110] Scott Higham, et al., Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse, Wash. Post (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.fcfc4951ecbe.
[111] Bernstein, et al., *supra* note 96.
[112] Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, *25.

- "Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash."

235. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Distributor Defendants not only acknowledged that they understood their obligations under the law, but they also further affirmed that their conduct was in compliance with those obligations.

236. The Distributor Defendants have also concealed and prevented discovery of information, including data from the ARCOS database that will confirm their identities and the extent of their wrongful and illegal activities.

237. The Pharmaceutical Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Pharmaceutical Defendants invented the concept of "pseudoaddiction" and promoted it to an unsuspecting medical community. The Pharmaceutical Defendants provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Pharmaceutical Defendants recommended to the medical community that dosages be increased, without disclosing the risks. The Pharmaceutical Defendants spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The medical community and consumers were misled by the Pharmaceutical Defendants' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing.

238. Defendants intended that their actions and omissions would be relied upon, including by affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

3. Fraudulent Concealment.

239. Plaintiff's claims are further subject to equitable tolling, stemming from Defendants knowingly and fraudulently concealing the facts alleged herein. As alleged herein, Defendants knew of the wrongful acts set forth above, and had material information pertinent to their discovery, and concealed them from Plaintiff and others.

240. The statute of limitations does not run on any causes of action asserted herein because Defendants have concealed information. Defendants are estopped from asserting any statute of limitations or prescriptive period as a defense because they intentionally concealed facts and engaged in fraudulent practices that prevented the discovery of their wrongful conduct.

241. The purposes of the statutes of limitations period and prescriptive periods, if any, are satisfied because Defendants cannot claim prejudice due to a late filing where Plaintiff filed suit promptly upon discovering all facts essential to its claims, described herein, which Defendants knowingly concealed.

242. In light of their statements to the media, in legal filings, and in settlements, it is plain that Defendants had actual or constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

243. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct.

244. The allegations set forth in this Complaint establish the liability of the Defendants unto Plaintiff under numerous causes of action set forth hereinafter. To the extent that any causes of action may be deemed to be inconsistent with any other causes of action, they shall be deemed to be pled in the alternative.

V. CAUSES OF ACTION

Count I: Violation of Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* (The "Opioid Marketing Enterprise") (Against the Pharmaceutical Defendants)

245. Plaintiff incorporates all allegations contained in this Complaint as if fully set forth herein.

246. Plaintiff, as a "person" who has been injured within the meaning of 18 U.S.C. § 1964(c), brings this claim for civil remedies under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), against the Pharmaceutical Defendants, each of whom is a "person" within the meaning of 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

247. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt."

248. Section 1962(d) of RICO makes it unlawful "for any person to conspire to violate" section 1962(c).

249. Beginning in the early 1990s, the Pharmaceutical Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully increasing the volume of opioids they sold. The Pharmaceutical Defendants knew that they could not increase their profits without misrepresenting that opioids were non-addictive and safe for the long-term treatment of chronic pain.

250. The generally accepted standards of medical practice prior to the 1990s dictated that opioids should only be used in short durations to treat acute pain, pain relating to recovery

from surgery, or for cancer or palliative (end-of-life) care. Due to the evidence of addiction and lack of evidence indicating that opioids improved patients' ability to overcome pain and function, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

251. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term, chronic, non-acute and non-cancer pain, the Pharmaceutical Defendants formed an enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term, chronic pain, in violation of 18 U.S.C. § 1962(c) (the "Opioid Marketing Enterprise").

A. THE OPIOID MARKETING ENTERPRISE

252. The term "enterprise" is defined as including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4).

253. The Pharmaceutical Defendants formed an association-in-fact enterprise along with certain advocacy groups and professional societies ("Front Groups") in order to unlawfully increase the demand for opioids.

254. In order to accomplish their common purpose, members of the Opioid Marketing Enterprise repeatedly and systematically misrepresented – affirmatively, and through half-truths and omissions – that opioids are non-addictive and safe for the effective treatment of long-term, chronic, non-acute and non-cancer pain, and for other off-label uses not approved by the FDA. The Opioid Marketing Enterprise misrepresented and concealed the serious risks and lack of corresponding benefits of using opioids for long-term, chronic pain. By making these

misrepresentations, the Opioid Marketing Enterprise ensured that a large number of opioid prescriptions would be written and filled for chronic pain.

255. The Opioid Marketing Enterprise consists of the Pharmaceutical Defendants and the Front Groups – including American Pain Foundation, American Academy of Pain Medicine, American Pain Society, Federation of State Medical Boards, U.S. Pain Foundation, and American Geriatrics Society.

256. Through their personal relationships, the Pharmaceutical Defendants and members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose. The Pharmaceutical Defendants' substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.[113]

257. The Pharmaceutical Defendants, through the Opioid Marketing Enterprise, made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use, including: (1) downplaying the serious risk of addiction; (2) creating and promoting the concept of "pseudo-addiction" when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerating the effectiveness of screening tools to prevent addiction; (4) claiming that opioid dependence and withdrawal are easily managed; (5) denying the risks of higher opioid dosages; and (6) exaggerating the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction.

[113] U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Members' Office, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups* 1 (2018), https://www.hsdl.org/?abstract&did=808171 [hereinafter *Fueling an Epidemic*].

258. The Pharmaceutical Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support the Pharmaceutical Defendants' claims.

259. The Pharmaceutical Defendants' scheme, and the common purpose of the Opioid Marketing Enterprise, has been wildly successful. Opioids are now the most-prescribed class of drugs. Globally, opioid sales generated $11 billion in revenue for drug companies in 2010 alone; sales in the United States have exceeded $8 billion in revenue annually since 2009.[114] In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."[115]

260. The scheme devised and implemented by the Pharmaceutical Defendants amounted to a common course of conduct designed to ensure that the Pharmaceutical Defendants unlawfully increased their sales and profits through misrepresentations about the addictive nature and effective use of the Pharmaceutical Defendants' drugs. As Senator McCaskill aptly recognized:

> The opioid epidemic is the direct result of a calculated marketing and sales strategy developed in the 90's, which delivered three simple messages to physicians. First, that chronic pain was severely undertreated in the United States. Second, that opioids were the best tool to address that pain. And third, that opioids could treat pain without risk of serious addiction. As it turns out, these messages were exaggerations at best and outright lies at worst.[116]

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[114] *See* Katherine Eban, *OxyContin: Purdue Pharma's Painful Medicine*, Fortune (Nov. 9, 2011), http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/; David Crow, *Drugmakers Hooked on $10bn Opioid Habit*, Fin. Times (Aug. 10, 2016), https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95.

[115] Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), http://i2.cdn.turner.com/cnn/2016/images/08/25/sg.opioid.letter.pdf; *see also Fueling an Epidemic*, *supra* note 113, at 1.

[116] *See LIVESTREAM: Insys Opioid Sales and Marketing Practices Roundtable*, YouTube (Sept. 12, 2017), at 31:03-31:37, https://www.youtube.com/watch?v=k9mrQa8_vAo.

261. The Opioid Marketing Enterprise is an ongoing and continuing organization that created and maintained systematic links and interpersonal relationships and engaged in a pattern of predicate acts (i.e. racketeering activity) in order to further the common purpose of the enterprise: unlawfully increasing profits and revenues from the continued prescription and use of opioids for long-term, chronic pain. Each of the entities who formed the Opioid Marketing Enterprise is a person within the meaning of 18 U.S.C. § 1962(c) and acted to enable the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

262. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each Pharmaceutical Defendant and its members; (b) was separate and distinct from the pattern of racketeering in which the Pharmaceutical Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the Pharmaceutical Defendants; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including between the Pharmaceutical Defendants and each of the Front Groups; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit.

263. At all relevant times, the Opioid Marketing Enterprise was engaged in, and its activities affected, interstate and foreign commerce.

264. The members of the Opioid Marketing Enterprise are systematically linked through contractual relationships, financial ties, personal relationships and continuing coordination of activities, as spearheaded by the Pharmaceutical Defendants.

265. Each of the Pharmaceutical Defendants and each member of the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and

continuing coordination of activities. Each of the Pharmaceutical Defendants coordinated their marketing efforts through the same Front Groups, based on their agreement and understanding that the Front Groups were industry friendly and would work together with the Pharmaceutical Defendants to advance the common purpose of the Opioid Marketing Enterprise.

266. In addition to their systematic links to and personal relationships with the Front Groups, described herein, the Pharmaceutical Defendants had systematic links to and personal relationships with each other through their participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities, including but not limited to, the Pain Care Forum ("PCF") and the Healthcare Distribution Alliance ("HDA").

267. The PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF, including the Pharmaceutical Defendants, quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

268. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[117] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[118]

[117] Matthew Perrone & Ben Wieder, *Pro-Painkiller Echo Chamber Shaped Policy Amid Drug Epidemic*, The Center for Public Integrity (Sept. 19, 2016), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echochamber-shaped-policy-amid-drug-epidemic (emphasis added).
[118] *Id.*

269. Not surprisingly, each of the Pharmaceutical Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.[119] In 2012, membership and participating organizations in the PCF included the HDA (of which all the Pharmaceutical Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company of Janssen Pharmaceuticals), and Teva (the parent company of Cephalon).[120] Each of the Pharmaceutical Defendants worked together through the PCF to advance the interests of the Opioid Marketing Enterprise. But, the Pharmaceutical Defendants were not alone; many of the Front Groups were also members of the PCF, including the American Academy of Pain Medicine, American Pain Foundation, and American Pain Society.

270. Through the PCF, the Pharmaceutical Defendants met regularly and in person to form and take action to further the common purpose of the Opioid Marketing Enterprise and shape the national response to the ongoing prescription opioid epidemic.

271. Through the HDA, the Pharmaceutical Defendants "strengthen[ed] . . . alliances"[121] and took actions to further the common purpose of the Opioid Marketing Enterprise.

272. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[122] Clearly, membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and "alliances" between the Pharmaceutical Defendants.

[119] Pain Care Forum, *2012 Meetings Schedule* (2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf.
[120] *Id.* Upon information and belief, Mallinckrodt became an active member of the PCF sometime after 2012.
[121] Murthy, *supra* note 115; *Fueling an Epidemic*, *supra* note 113, at 1.
[122] *See LIVESTREAM*, *supra* note 116.

273. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Pharmaceutical Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the Opioid Marketing Enterprise.

274. The HDA also offered multiple conferences, including annual business and leadership conferences through which the Pharmaceutical Defendants had an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[123] The HDA and its conferences were significant opportunities for the Pharmaceutical Defendants to interact at the executive level and form and take actions in furtherance of the common purpose of the Opioid Marketing Enterprise. It is clear that the Pharmaceutical Defendants embraced this opportunity by attending and sponsoring these events.[124]

275. The systematic contacts and personal relationships developed by the Pharmaceutical Defendants through the PCF and the HDA furthered the common purpose of the Opioid Marketing Enterprise because it allowed the Pharmaceutical Defendants to coordinate the conduct of the Opioid Marketing Enterprise by, including but not limited to, coordinating their interaction and development of relationships with the Front Groups.

276. Each of the Pharmaceutical Defendants had systematic links to and personal relationships with Front Groups that operated as part of the Opioid Marketing Enterprise to further the common purpose of unlawfully increasing sales by misrepresenting the non-addictive and

[123] *Business and Leadership Conference – Information for Manufacturers*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-formanufacturers (last accessed Sept. 14, 2017).
[124] *See 2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-distribution-management-conference (last accessed Sept. 14, 2017).

effective use of opioids for the treatment of long-term, chronic pain. As recently reported by the U.S. Senate:

> The fact that these same manufacturers provided millions of dollars to the groups described below suggests, at the very least, a direct link between corporate donations and the advancement of opioids-friendly messaging. By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic.[125]

277. But, the Pharmaceutical Defendants' connection with and control over the Front Groups did not end with financial contributions. Rather, the Pharmaceutical Defendants made substantial contributions to physicians affiliated with the Front Groups totaling more than $1.6 million.[126] Moreover, the Pharmaceutical Defendants "made substantial payments to individual group executives, staff members, board members, and advisory board members" affiliated with the Front Groups subject to the Senate Committee's study.[127]

278. As described in more detail herein, the Pharmaceutical Defendants "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain."[128] They also "lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding."[129]

279. Patient advocacy organizations and professional societies like the Front Groups "play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public."[130] "Even small organizations –

[125] *Fueling an Epidemic*, *supra* note 113, at 1.
[126] *Id.* at 3.
[127] *Id.* at 10.
[128] *Id.* at 12-15.
[129] *Id.* at 12.
[130] *Id.* at 2.

with 'their large numbers and credibility with policymakers and the public' – have 'extensive influence in specific disease areas.' Larger organizations with extensive funding and outreach capabilities 'likely have a substantial effect on policies relevant to their industry sponsors.'"[131] Indeed, the U.S. Senate's report found that the Pharmaceutical Defendants made nearly $9 million worth of contributions to various Front Groups, including members of the Opioid Marketing Enterprise.[132]

280. The Front Groups included in the Opioid Marketing Enterprise "have promoted messages and policies favorable to opioid use while receiving millions of dollars in payments from opioid manufacturers. Through criticism of government prescribing guidelines, minimization of opioid addiction risk, and other efforts, ostensibly neutral advocacy organizations have often supported industry interests at the expense of their own constituencies."[133] Many of the Pharmaceutical Defendants' Front Groups received the largest contributions.

281. The systematic contacts and interpersonal relationships of the Pharmaceutical Defendants and the Front Groups are further described below:

282. The American Pain Foundation ("APF") was the most prominent member of the Front Groups and was funded almost exclusively by the Pharmaceutical Defendants, receiving more than $10 million in funding from the Pharmaceutical Defendants between 2007 and the close of its business in May 2012. APF had multiple contacts and personal relationships with the Pharmaceutical Defendants through its many publishing and educational programs, funded and supported by the Pharmaceutical Defendants. On information and belief, between 2009 and 2010, APF received more than eighty percent of its operating budget from pharmaceutical industry

[131] *Id.*
[132] *Id.* at 3.
[133] *Id.*

sources. By 2011, upon information and belief, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others.

283. On information and belief, APF was often called upon to provide "patient representatives" for the Pharmaceutical Defendants' promotional activities, including for Purdue's "Partners Against Pain" and Janssen's "Let's Talk Pain." APF functioned largely as an advocate for the interests of the Pharmaceutical Defendants, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

284. APF is also credited with creating the PCF in 2004. On information and belief, former APF President Will Rowe described the PCF as "a deliberate effort to positively merge the capacities of industry, professional associations, and patient organizations."

285. Upon information and belief, representatives of the Pharmaceutical Defendants, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

286. In December 2011, a ProPublica investigation found that in 2010, nearly 90% of APF's funding came from the drug and medical device community, including Pharmaceutical Defendants.[134] More specifically, APF received approximately $2.3 million from industry sources out of total income of $2.85 million in 2009. Its budget for 2010 projected receipt of approximately $2.9 million from drug companies, out of total income of approximately $3.5 million. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial

[134] Charles Ornstein & Tracy Weber, *Patient Advocacy Group Funded By Success of Painkiller Drugs, Probe Finds*, Wash. Post (Dec. 23, 2011), https://www.washingtonpost.com/national/healthscience/patient-advocacy-groupfunded-by-success-of-painkiller-drugs-probefinds/2011/12/20/gIQAgvczDP_story.html?utm_term=22049984c606.

and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."[135]

287. The American Academy of Pain Medicine ("AAPM") was another Front Group that had systematic ties and personal relationships with the Pharmaceutical Defendants. AAPM's corporate council includes Purdue, Depomed, Teva and other pharmaceutical companies. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM described the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allowed drug company executives and marketing staff to meet with AAPM executive committee members in small settings. The Pharmaceutical Defendants were all members of the council and presented deceptive programs to doctors who attended this annual event.[136]

288. The Pharmaceutical Defendants internally viewed AAPM as "industry friendly," with Defendants' advisors and speakers among its active members. The Pharmaceutical Defendants attended AAPM conferences, funded its CMEs and satellite symposia, and distributed its publications. AAPM conferences heavily emphasized sessions on opioids.

[135] Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Ties to Pain Groups*, Wash. Post (May 8, 2012), https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companiesties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html.

[136] The American Academy of Pain Medicine, *Pain Medicine DC The Governing Voices of Pain: Medicine, Science, and Government* (2011), http://www.painmed.org/files/2011-annual-meeting-programbook.pdf.

289. Upon information and belief, representatives of the Pharmaceutical Defendants, often at informal meetings at conferences, suggested activities and publications for AAPM to pursue. AAPM then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

290. The American Pain Society ("APS") was another Front Group with systematic connections and interpersonal relationships with the Pharmaceutical Defendants. APS was one of the Front Groups investigated by Senators Grassley and Baucus, as evidenced by their May 8, 2012 letter arising out of their investigation of "extensive ties between companies that manufacture and market opioids and non-profit organizations" that "helped created a body of dubious information favoring opioids."[137]

291. Upon information and belief, representatives of the Pharmaceutical Defendants, often at informal meetings at conferences, suggested activities and publications for APS to pursue. APS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

292. The Federation of State Medical Boards ("FSMB") was another Front Group with systematic connections and interpersonal relationships with the Pharmaceutical Defendants. In addition to the contributions reported in *Fueling an Epidemic*, a June 8, 2012 letter submitted by FSMB to the Senate Finance Committee disclosed substantial payments from the Pharmaceutical Defendants beginning in 1997 and continuing through 2012.[138] Not surprisingly, the FSMB was

[137] Letter from U.S. Senators Charles E. Grassley and Max Baucus to Catherine Underwood, Executive Director, American Pain Society (May 8, 2012), https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American%20Pain%20Society.pdf.

[138] Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley (June 8, 2012).

another one of the Front Groups investigated by Senators Grassley and Baucus, as evidenced by their May 8, 2012 letter arising out of their investigation of "extensive ties between companies that manufacture and market opioids and non-profit organizations" that "helped created a body of dubious information favoring opioids."[139]

293. The U.S. Pain Foundation ("USPF") was another Front Group with systematic connections and interpersonal relationships with the Pharmaceutical Defendants. The USPF was one of the largest recipients of contributions from the Pharmaceutical Defendants, collecting nearly $3 million in payments between 2012 and 2015 alone.[140] The USPF was also a critical component of the Opioid Marketing Enterprise's lobbying efforts to reduce the limits on over-prescription. USPF advertised its ties to the Pharmaceutical Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (i.e., Janssen), and Mallinckrodt as "Platinum," "Gold," and "Basic" corporate members.[141] Industry Front Groups like the American Academy of Pain Management, AAPM, APS, and PhRMA are also members of varying levels in the USPF.

294. American Geriatrics Society ("AGS") was another Front Group with systematic connections and interpersonal relationships with the Defendants. AGS was a large recipient of contributions from the Pharmaceutical Defendants, including Endo, Purdue and Janssen. AGS contracted with the Pharmaceutical Defendants to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (The Management of Persistent Pain in Older Persons) and 2009 (Pharmacological Management of Persistent Pain in Older Persons[142]). According to news reports,

[139] Letter from U.S. Senators Charles E. Grassley and Max Baucus to Catherine Underwood, Executive Director, American Pain Society, *supra* note 137.
[140] *Fueling an Epidemic*, *supra* note 113, at 4.
[141] *Id.* at 12; *Transparency*, U.S. Pain Found., https://uspainfoundation.org/transparency/ (last accessed Mar. 9, 2018).
[142] *Pharmacological Management of Persistent Pain in Older Persons*, 57 J. Am. Geriatrics Soc'y 1331, 1339, 1342 (2009), https://www.nhqualitycampaign.org/files/AmericanGeriatricSociety-PainGuidelines2009.pdf.

AGS has received at least $344,000 in funding from opioid manufacturers since 2009.[143] AGS's complicity in the common purpose of the Opioid Marketing Enterprise is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive upfront funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate pro-opioid publications.

295. Upon information and belief, representatives of the Pharmaceutical Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

296. There was regular communication between each of the Pharmaceutical Defendants and Front Groups in which information was shared, misrepresentations were coordinated and payments were exchanged, and in which the Pharmaceutical Defendants and Front Groups shared information necessary to overcome objections and resistance to the use of opioids for chronic pain. The Pharmaceutical Defendants and Front Groups functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed to take actions to hide the scheme and continue its existence.

297. At all relevant times, the Front Groups were aware of the Pharmaceutical Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and Plaintiff. But for the Opioid Marketing Enterprise's unlawful fraud, the Front Groups would have had incentive

[143] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee J. Sentinel (May 30, 2012).

to disclose the deceit by the Pharmaceutical Defendants and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose and reaped substantial benefits.

298. Each member of the Opioid Marketing Enterprise furthered the common purpose of the enterprise by publishing and disseminating statements that minimized the risk of addiction and misrepresented the safety of using prescription opioids for long-term treatment of chronic, non-acute, and non-cancer pain.

299. The foregoing evidences that the Pharmaceutical Defendants and the Front Groups were each willing participants in the Opioid Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Opioid Marketing Enterprise's purpose.

300. The scheme devised and implemented by the Pharmaceutical Defendants and members of the Opioid Marketing Enterprise amounted to a common course of conduct intended to increase the Pharmaceutical Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term, chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

B. THE CONDUCT OF THE OPIOID MARKETING ENTERPRISE

301. During the time period described in this Complaint, from approximately the late 1990s to the present, the Pharmaceutical Defendants conducted or participated, directly or indirectly, in the conduct of the Opioid Marketing Enterprise's affairs, within the meaning of 18 U.S.C. § 1962(c).

302. The Pharmaceutical Defendants exerted control over the Opioid Marketing Enterprise and participated in the operation or management of the affairs of the Opioid Marketing Enterprise in the following ways:

- Creating a body of deceptive, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to be relied upon by physicians, patients, and payors;
- Creating a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to be relied upon by physicians, patients, and payors;
- Creating a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to be relied upon by physicians, patients, and payors;
- Creating a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to be relied upon by physicians, patients, and payors;
- Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the Pharmaceutical Defendants' messages about the use of opioids for chronic pain;

- Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the Pharmaceutical Defendants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;
- Paying significant amounts of money to the leaders and individuals associated with Front Groups;
- Donating to Front Groups to support talks or CMEs that were typically presented over meals or at conferences;
- Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;
- Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;
- Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the Pharmaceutical Defendants, such as veterans and the elderly, and then funding that distribution;
- Concealing their relationship to and control of Front Groups from Plaintiff and the public at large; and
- Intending that Front Groups would distribute promotional and other materials that claimed opioids could be safely used for chronic pain.

303. The Front Groups also participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

- The Front Groups promised to, and did, make representations regarding opioids and the Pharmaceutical Defendants' drugs that were consistent with the Pharmaceutical Defendants' messages;
- The Front Groups distributed promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction and misrepresented that the benefits of using opioids for chronic pain outweighed the risks;
- The Front Groups echoed and amplified messages favorable to increased opioid use – and ultimately, the financial interests of the Pharmaceutical Defendants;
- The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;
- The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- The Front Groups concealed their connections to the Pharmaceutical Defendants.

304. The Pharmaceutical Defendants' Front Groups, "with their large numbers and credibility with policymakers and the public – have 'extensive influence in specific disease areas.'" The Pharmaceutical Defendants' larger Front Groups "likely have a substantial effect on policies relevant to their industry sponsors."[144] "By aligning medical culture with industry goals in this way, many of the groups . . . may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."[145]

C. PATTERN OF RACKETEERING ACTIVITY

[144] *Fueling an Epidemic*, *supra* note 113, at 1.
[145] *Id.* at 2.

305. Each of the Pharmaceutical Defendants conducted and participated in the conduct of the affairs of the Opioid Marketing Enterprise through a "pattern of racketeering activity," as defined in 18 U.S.C. § 1961(5) and as prohibited by 18 U.S.C. § 1962(c).

306. The Pharmaceutical Defendants' common purpose and fraudulent scheme violated RICO in a number of ways. The Pharmaceutical Defendants engaged in multiple, repeated and continuous violations of the federal mail and wire fraud statutes, 18 U.S.C. §§ 1341, 1343, each of which constitutes a predicate act of racketeering activity pursuant to 18 U.S.C. § 1961(1).

307. The Pharmaceutical Defendants committed, conspired to commit, and/or aided and abetted others in the violation of at least two predicate acts of racketeering activity (i.e. mail and/or wire fraud) within a ten-year period.

308. The multiple acts of racketeering activity that the Pharmaceutical Defendants committed, conspired to commit, and/or aided and abetted others in violation of were related to each other and posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity."

309. The Pharmaceutical Defendants committed these predicate acts, which number in the thousands, intentionally and knowingly and with the specific intent to advance the Opioid Marketing Enterprise.

310. The predicate acts all had the purpose of generating significant revenue and profits for the Pharmaceutical Defendants while Plaintiff was left with substantial injury to its business through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the Pharmaceutical Defendants through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme. The predicate acts were related and not isolated events.

311. The last predicate act occurred within ten years of the commission of a prior predicate act.

312. The Pharmaceutical Defendants used the United States mail service and interstate wires to send and receive thousands of communications, publications, representations, statements, electronic transmissions, and payments to carry out the fraud of the Opioid Marketing Enterprise, as outlined below and throughout this Complaint.

313. The Pharmaceutical Defendants, through the Opioid Marketing Enterprise, made fraudulent and misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use, including, inter alia: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that screening questions and professional guidelines help curb addiction and potential abuse; (4) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the Pharmaceutical Defendants named "pseudo-addiction"; (5) that withdrawal is easily managed; (6) that increased dosing presents no significant risks; (7) that long-term use of opioids improves function, including but not limited to psychological health and health-related quality of life; (8) that opioids are safe and effective for long-term treatment of chronic, non-acute and non-cancer pain; (9) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; and (10) that abuse-deterrent formulations provide a solution to opioid abuse.

314. In each of the actions performed by members of the Opioid Marketing Enterprise described above, the members of the Opioid Marketing Enterprise made branded and unbranded marketing claims about prescription opioids that misrepresented prescription opioids as non-addictive and safe for use, identified below and throughout this Complaint.

315. Unbranded marketing misrepresentations about the benefits and risks of opioid use made in furtherance of the Opioid Marketing Enterprise's common purpose include:

a. members of the Opioid Marketing Enterprise minimizing the risks of addiction and/or construing opioids as non-addictive;

b. members of the Opioid Marketing Enterprise advocating that opioids were safe and effective for long-term treatment of chronic, non-acute and non-cancer pain;

c. members of the Opioid Marketing Enterprise creating and championing the concept of "pseudo-addiction" and advocating that signs of addiction were actually pseudo-addiction that required prescribing additional opioids;

d. members of the Opioid Marketing Enterprise advocating that long-term use of prescription opioids would improve function, including but not limited to psychological health and health-related quality of life;

e. members of the Opioid Marketing Enterprise representing that screening questions and professional guidelines would help curb addiction and potential abuse.

316. In addition to the unbranded marketing misrepresentations made by members of the Opioid Marketing Enterprise, the Pharmaceutical Defendants made misrepresentations in their branded marketing activities. The Pharmaceutical Defendants' branded marketing misrepresentations include:

a. the Pharmaceutical Defendants misrepresenting that opioids were non-addictive or posed less risk of addiction or abuse;

b. the Pharmaceutical Defendants misrepresenting that opioids improved function and quality of life;

c. the Pharmaceutical Defendants misrepresenting that addiction risks can be avoided or managed through screening tools and prescription guidelines;

d. the Pharmaceutical Defendants misrepresenting that signs of opioid addiction were not addiction and that withdrawal could be simply managed, and promoting the concept of pseudo-addiction;

e. the Pharmaceutical Defendants misrepresenting that opioids were safer than non-opioid analgesics because there is no ceiling dose for opioid treatment.

317. Because the Pharmaceutical Defendants disguised their participation in the Opioid Marketing Enterprise and worked to keep the Opioid Marketing Enterprise's existence secret so as to give the false appearance that their fraudulent messages reflected the views of independent third parties, many of the precise dates of the Opioid Marketing Enterprise's uses of the United States mail and interstate wires (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by the Pharmaceutical Defendants and Front Groups. Indeed, an essential part of the successful operation of the Opioid Marketing Enterprise depended upon secrecy.

318. Despite the Pharmaceutical Defendants' concealment, Plaintiff provides representative examples below and throughout this Complaint of the Pharmaceutical Defendants' dissemination of misrepresentations and false statements to Plaintiff, other health care providers, prescribers, regulators and consumers, and how those acts were in furtherance of the scheme.

319. By way of example, some of the specific fraudulent misrepresentations, branded and unbranded, regarding the risks of opioid addiction made by the Pharmaceutical Defendants (in addition to all of the other conduct described in this Complaint) include the following:

a. Purdue produced a promotional video for OxyContin in 1998 that stated that "the rate of addiction amongst pain patients who are treated by doctors is much less than 1%" and that opioids "do not have serious medical side effects."[146]

b. Actavis distributed a patient education brochure that claimed opioid addiction is "less likely if you have never had an addiction problem."

c. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain, which claimed that addiction is rare and limited to extreme cases of unauthorized doses.[147]

d. Painknowledge.com, a website sponsored by Endo, claimed that "[p]eople who take opioids as prescribed usually do not become addicted."

e. Purdue's unbranded website "Partners Against Pain" stated that it was a "[m]yth" that "[o]pioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids."

f. Abbott trained its sales staff to tell physicians that OxyContin had fewer of the euphoric side effects associated with the shorter-acting painkiller Vicodin, including Abbott's "King of Pain," Jerry Eichhorn, telling his staff of "Royal Crusaders" that OxyContin would "minimiz[e] the risk of dependence" and "lower[] euphoria," when, in fact, he had little knowledge of pharmacology and no basis for these statements.[148]

g. Endo authored a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain which stated that "most people do not develop an addiction problem."

[146] *I Got My Life Back*, Purdue Pharma OxyContin Commercial, https://www.youtube.com/watch?v=Er78Dj5hyeI (last accessed Apr. 17, 2019).
[147] Fishman, *supra* note 36; *Treatment Options*, *supra* note 36..
[148] Armstrong, *supra* note 40.

h. Depomed promoted the use of Nucynta as a safer, less addictive, less abusive alternative to other opioids and claimed it did not contain the same euphoric feeling as other opioids.

i. Janssen distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults which described as "myth" the claim that opioids are addictive.[149]

j. Mallinckrodt's C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance promoted a book entitled Defeat Chronic Pain Now! which claimed that "[w]hen chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving" and "[o]nly a minority of chronic pain patients who are taking long-term opioids develop tolerance."

k. One Janssen website claimed that concerns about opioid addiction were "overestimated."

l. Janssen's website for Duragesic stated, "Addiction is relatively rare when patients take opioids appropriately," in response to a hypothetical patient's concern that he would "become a drug addict."

m. Until 2012, Endo website www.opana.com stated that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."

n. Another Endo website, PainAction.com, stated that "[m]ost chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

[149] Finding Relief Pain Management for Older Adults, *supra*.

o. Janssen's unbranded website "Prescribe Responsibly" stated that concerns about addiction were "overestimated" and that "true addiction occurs only in a small percentage of patients."[150]

p. Depomed's Senior Vice President and Chief Financial Officer, August Moretti, told investors that "[a]lthough not in the label, there's a very low abuse profile and side effect rate" for Nucynta.

q. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that pain is undertreated due to "misconceptions about opioid addiction."[151]

320. By way of example, some of the specific fraudulent misrepresentations regarding the ability to safely increase opioid dosages indefinitely without added risk of addiction and other health consequences made by the Pharmaceutical Defendants (in addition to all of the other conduct described in this Complaint) include the following:

a. Actavis distributed a patient brochure that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction."

b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain, which claimed that some patients need larger doses of opioids, with "no ceiling dose" for appropriate treatment of severe, chronic pain.[152]

c. Painknowledge.com, a website sponsored by Endo, claimed that opioid dosages may be increased until "you are on the right dose of medication for your pain."

[150] Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, PRESCRIBE RESPONSIBLY, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last modified July 2, 2015).
[151] *A Policymaker's Guide to Understanding Pain*, *supra* note 38.
[152] *Treatment Options*, *supra* note 36.

d. Endo authored a pamphlet entitled Understanding Your Pain: Taking Oral Opioid Analgesics that stated, "The dose can be increased. . . . You won't 'run out' of pain relief."[153]

e. Janssen distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults that listed dosage limitations as "disadvantages" of other pain medicines yet omitted any discussion of risks of increased opioid dosages.[154]

f. Purdue's "In the Face of Pain" website promoted the notion that if a patient's doctor did not prescribe what, in the patient's view, was a sufficient dosage of opioids, he or she should find another doctor who would.

g. Purdue's A Policymaker's Guide to Understanding Pain & Its Management stated that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages.[155]

h. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence challenging the correlation between opioid dosage and overdose.

i. Purdue advised prescribers that "dose adjustments may be made every 1-2 days" and the "total daily dose can usually be increased by 25% to 50%" without addressing the increased risk of respiratory depression and death from the increased dose.[156]

321. By way of example, some of the specific fraudulent misrepresentations, branded and unbranded, regarding how addiction risk can be effectively screened, managed, and/or

[153] McCaffery & Pasero, *supra* note 50.
[154] Finding Relief Pain Management for Older Adults, *supra*.
[155] *A Policymaker's Guide to Understanding Pain*, *supra* note 38.
[156] Purdue Pharma, L.P., *OxyContin Risk Evaluation and Mitigation Strategy* (2010), https://web.archive.org/web/20170215190303/http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf.

prevented made by the Pharmaceutical Defendants (in addition to all of the other conduct described in this Complaint) include the following:

a. Purdue's webinar, Managing Patient's Opioid Use: Balancing the Need and Risk, claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

b. Endo sponsored a supplement in 2007 in the Journal of Family Practice that emphasized the effectiveness of screening tools to avoid addictions.

c. Purdue's unbranded website "Partners Against Pain" stated, "Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids."

d. Cephalon sponsored a CME presentation offered by Medscape in 2003 entitled Pharmacologic Management of Breakthrough or Incident Pain that taught that "[c]linicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse" and "[t]he concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse."[157]

e. Purdue represented in scientific conferences that "bad apple" patients – and not opioids – were the source of the addiction crisis.

f. Mallinckrodt's C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance promoted a book entitled Defeat Chronic Pain Now! which asserted as "[t]he

[157] Michael J. Brennan, et al., *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, http://www.medscape.org/viewarticle/449803.

bottom line" that "[o]nly rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction" and as "fact[]" that "[i]t is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

g. Purdue's COO told members of the United States Congress in 2001 that although there had been "a number of cases" of "overdoses and deaths[, v]irtually all of th[o]se reports involve[d] people who [were] abusing the medication, not patients with legitimate medical needs."[158]

322. By way of example of specific fraudulent misrepresentations, branded and unbranded, regarding the existence of "pseudo-addiction" made by the Pharmaceutical Defendants (in addition to all of the other conduct described in this Complaint), Janssen sponsored, funded, and edited a website entitled "Let's Talk Pain" in 2009 that defined "pseudo-addiction" as "patient behaviors that may occur when pain is undertreated" and stated that it was "different from true addiction because such behaviors [could] be resolved with effective pain management," and Purdue circulated an unbranded pamphlet entitled Clinical Issues in Opioid Prescribing from in or about 2005 to in or about 2013 that listed "illicit drug use and deception" as evidence of "pseudo-addiction" caused by untreated pain, not true addiction.

323. By way of example, some of the specific fraudulent misrepresentations regarding how withdrawal could be easily managed made by the Pharmaceutical Defendants (in addition to all of the other conduct described in this Complaint) include a CME sponsored by Endo entitled

[158] *Oxcontin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operation Officer, Purdue Pharma, L.P.), https://www.govinfo.gov/content/pkg/CHRG-107hhrg75754/html/CHRG-107hhrg75754.htm.

Persistent Pain in the Older Adult which claimed that withdrawal symptoms could be avoided by tapering a patient's opioid dose by up to 20% for a few days and APF's A Policymaker's Guide to Understanding Pain & Its Management, sponsored by Purdue, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," without mentioning any known or foreseeable issues.[159]

324. By way of example, some of the specific fraudulent misrepresentations regarding how the long-term use of opioids could improve patients' function and quality of life made by the Pharmaceutical Defendants (in addition to all of the other conduct described in this Complaint) include the following:

a. Actavis advertised that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on [their] bod[ies] and [their] mental health" and help patients enjoy their lives.

b. Endo advertised that the use of Opana ER for chronic pain would allow patients to perform demanding tasks and portrayed seemingly healthy, unimpaired persons.

c. Janssen distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults that stated as "a fact" that "opioids may make it easier for people to live normally," including the ability to partake in activities such as sleeping peacefully, working, recreating, having sex, walking, and climbing stairs.

d. Janssen promoted Duragesic as able to provide patients with "[w]ork, uninterrupted," "[l]ife, uninterrupted" and "[g]ame, uninterrupted," and to improve "physical" and "social functioning."

[159] *See A Policymaker's Guide to Understanding Pain*, *supra* note 38.

e. Purdue created advertisements for OxyContin called "Pain Vignettes" that implied that OxyContin improves patients' function.

f. "Responsible Opioid Prescribing," by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.

g. Cephalon and Purdue sponsored APF's "Treatment Options: A Guide for People Living with Pain," which counseled patients that opioids "give [pain patients] a quality of life [they] deserve."

h. Purdue ran a full-page advertisement for OxyContin in the Journal of the American Medical Association that proclaimed "There Can Be Life With Relief" and depicted a man fly-fishing.[160]

i. Painknowledge.com, a website sponsored by Endo, claimed that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse."

j. Endo offered CMEs entitled Persistent Pain in the Older Patient which claimed that chronic opioid therapy had been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

k. Janssen sponsored, funded, and edited a website entitled "Let's Talk Pain" in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

l. Purdue's A Policymaker's Guide to Understanding Pain & Its Management claimed that "multiple clinical studies" had shown opioids as effective in improving daily

[160] Adams, *supra* note 63.

function, psychological health, and health-related quality of life for chronic pain patients.[161]

m. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives conveyed the message that opioids would improve patient function to medical providers on numerous occasions.

n. To this day, Mallinckrodt's website claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."[162]

325. By way of example, some specific fraudulent misrepresentations, branded and unbranded, that opioids are safe and effective for long-term treatment of chronic, non-acute and non-cancer pain made by the Pharmaceutical Defendants (in addition to all of the other conduct described in this Complaint) include the following:

a. Purdue claimed on its unbranded website "Partners Against Pain" that addiction risk "appears to be low when opioids are dosed properly for chronic, non-cancer pain."

b. Cephalon promoted Actiq to health care providers for non-cancer patients to use for conditions like migraines and filing of a supplemental drug application in 2008 requesting FDA approval for Fentora for the treatment of non-cancer BTP.

c. Depomed marketed Lazanda to physicians for treatment of non-cancer pain even though it is only indicated for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[163]

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[161] *A Policymaker's Guide to Understanding Pain*, *supra* note 38.
[162] *Responsible Use*, Mallinckrodt Pharms., http://www.mallinckrodt.com/corporate-responsibility/responsible-use (last accessed Apr. 17, 2019).
[163] *See First Fentanyl Nasal Spray Approved for Cancer Breakthrough Pain*, *supra* note 72.

326. By way of example, some specific fraudulent misrepresentations suggesting that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids made by the Pharmaceutical Defendants (in addition to all of the other conduct described in this Complaint) include a CME sponsored by Purdue and Endo that the American Medical Association offered in 2003, 2007, 2010, and 2013 entitled Overview of Management Options that taught that NSAIDs and other drugs, but not opioids, were unsafe at high dosages and APF's A Policymaker's Guide to Understanding Pain & Its Management, sponsored by Purdue and Cephalon, which warned that risks of NSAIDs increase if "taken for more than a period of months" and (falsely) attributed 10,000 to 20,000 deaths annually to NSAID overdose, with no corresponding warning for opioids.

327. By way of example, some specific fraudulent misrepresentations that abuse-deterrent formulations provide a solution to opioid abuse made by the Pharmaceutical Defendants (in addition to all of the other conduct described in this Complaint) include the following:

a. Purdue sales representatives represented to health care providers and prescribers that its reformulated OxyContin prevented tampering, in that it could not be crushed or snorted, and that it was non-addictive or less addictive than the previous formulation.

b. Endo filed a citizen petition with the FDA and published a press release claiming that its reformulated Opana ER had safety advantages because it was less crushable.

c. Mallinckrodt advertised that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving" [164] and "XARTEMIS XR has technology that requires abusers to exert additional effort to

[164] *Press Release*, Medtronic (Aug. 27, 2012), http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159.

extract the active ingredient from the large quantity of inactive deterrent ingredients."[165]

328. In addition to making unbranded and branded misrepresentations to consumers, the Opioid Marketing Enterprise undertook to perpetuate its fraud about the benefits and risks of opioids by undermining government regulation on the subject. Members of the Opioid Marketing Enterprise criticized and undermined the CDC Guidelines, which represented "an important step – and perhaps the first major step from the federal government – toward limiting opioid prescriptions for chronic pain."[166] The following are examples of the actions taken by Opioid Marketing Enterprise members to prevent restriction on over-prescription:

- Several Front Groups, including USPF and AAPM, criticized the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines."[167]
- AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence."[168]

329. These fraudulent misrepresentations, and the legion of other representations made by the Pharmaceutical Defendants and members of Opioid Marketing Enterprise outlined in this Complaint and elsewhere, all furthered the common purpose and fraudulent scheme of the Opioid

[165] Mallinckrodt Pharms., *Responsible Use of Opioid Pain Medications* (2014).
[166] *Fueling an Epidemic*, *supra* note 113, at 13.
[167] Pat Anson, *Chronic Pain Group Blasts CDC for Opioid Guidelines*, Pain News Network (Sept. 22, 2015), https://www.painnewsnetwork.org/stories/2015/9/22/chronic-pain-groups-blast-cdc-for-opioid-guidelines.
[168] Thomas G. Ciccone, *Responses and Criticisms Over New CDC Opioid Prescribing Guidelines*, Practical Pain Management (Mar. 17, 2016), https://www.practicalpainmanagement.com/resources/news-and-research/responses-criticisms-over-new-cdc-opioid-prescribing-guidelines.

Marketing Enterprise. But they were demonstrably false, as confirmed by investigations and enforcement actions against the Pharmaceutical Defendants.

330. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin in what the company acknowledged was an attempt to mislead doctors about the risk of addiction. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction and was unsupported by science.

331. Additionally, Michael Friedman, the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R. Udell, Purdue's top lawyer, pled guilty and agreed to pay $8 million in fines; and Paul D. Goldenheim, its former medical director, pled guilty and agreed to pay $7.5 million in fines.[169]

332. Purdue pled guilty to illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers, while Friedman, Udell and Goldenheim pled guilty to the misdemeanor charge of introducing misbranded drugs into interstate commerce, in violation of 21 U.S.C. §§ 331(a), 333(a)(1)-(2) and 352(a), for misbranding OxyContin.

333. In a statement announcing Purdue's guilty plea, John Brownlee, the U.S. Attorney for the Western District of Virginia, stated:

> Purdue claimed it had created the miracle drug – a low risk drug that could provide long acting pain relief but was less addictive and less subject to abuse. Purdue's marketing campaign worked, and sales for OxyContin skyrocketed – making billions for Purdue and millions for its top executives.
>
> But OxyContin offered no miracles to those suffering in pain. Purdue's claims that OxyContin was less addictive and less subject to abuse and diversion were false – and Purdue knew its claims were false. The result of their misrepresentations and

[169] Barry Meier, *Narcotic Maker Guilty of Deceit Over Marketing*, N.Y. Times (May 11, 2007), https://www.nytimes.com/2007/05/11/business/11drug.html.

> crimes sparked one of our nation's greatest prescription drug failures. . . . OxyContin was the child of marketers and bottom line financial decision making.[170]

334. Brownlee characterized Purdue's criminal activity as follows:

> First, Purdue trained its sales representatives to falsely inform health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse. Purdue ordered this training even though its own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet by simply crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.
>
> Second, Purdue falsely instructed its sales representatives to inform health care providers that OxyContin could create fewer chances for addiction than immediate-release opioids.
>
> Third, Purdue sponsored training that falsely taught Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids.
>
> Fourth, Purdue falsely told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug.
>
> And fifth, Purdue falsely told health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.[171]

335. Similarly, Endo's marketing of Opana ER was criticized and punished by the FDA and New York Attorney General. On February 18, 2017, the State of New York announced a settlement with Endo requiring it "to cease all misrepresentations regarding the properties of Opana ER [and] to describe accurately the risk of addiction to Opana ER."[172] In the Assurance of

[170] Press Release, U.S. Attorney for the Western District of Virginia, Statement of United States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executives for Illegally Misbranding OxyContin (May 10, 2007), https://assets.documentcloud.org/documents/279028/purdue-guilty-plea.pdf.
[171] *Id.*
[172] Press Release, New York Attorney General Eric T. Schneiderman, A.G. Schneiderman Announces Settlement With Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing Of Prescription Opioid Drugs (Mar. 3, 2016), https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals.

Discontinuance that effectuated the settlement, the State of New York stated that Endo knew about the risks arising from the reformulated Opana ER even before it received FDA approval. Among other things, the investigation concluded that:

- Endo improperly marketed Opana ER as designed to be crush resistant, when Endo's own studies dating from 2009 and 2010 showed that the pill could be crushed and ground;
- Endo improperly instructed its sales representatives to diminish and distort the risks associated with Opana ER, including the serious danger of addiction; and
- Endo made unsupported claims comparing Opana ER to other opioids and failed to disclose accurate information regarding studies addressing the negative effects of Opana ER.[173]

336. The 2017 settlement also identified and discussed a February 2013 communication from a consultant hired by Endo to the company, in which the consultant concluded that "[t]he initial data presented do not necessarily establish that the reformulated Opana ER is tamper resistant." The same consultant also reported that the distribution of the reformulated Opana ER had already led to higher levels of abuse of the drug via injection.[174]

337. The Office of the Attorney General of New York also revealed that the "managed care dossier" Endo provided to formulary committees of healthcare plans and pharmacy benefit managers misrepresented the studies that had been conducted on Opana ER. According to Endo's vice president for pharmacovigilance and risk management, the dossier was presented as a complete compendium of all research on the drug. However, it omitted certain studies: Study 108 (completed in 2009) and Study 109 (completed in 2010), which showed that reformulated Opana ER could be ground and chewed.

[173] *Id.*

[174] Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 6, *In the Matter of Endo Health Sols Inc. & Endo Pharms. Inc.*, No. 15-228 (Mar. 1, 2016), https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf

338. The settlement also detailed Endo's false and misleading representations about the non-addictiveness of opioids and Opana. For example, until April 2012, Endo's website for the drug, www.opana.com, contained the following representation: "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."[175] However, Endo neither conducted nor possessed a survey demonstrating that most healthcare providers who treat patients with pain agree with that representation.

339. The Office of the Attorney General of New York also disclosed the following facts that it determined to violate Opana's obligations to truthfully market its products:

- Training materials provided by Endo to sales representatives stated: "[s]ymptoms of withdrawal do not indicate addiction."[176] This representation is inconsistent with the diagnosis of opioid-use disorder as provided in the Diagnostic and Statistical Manual of Mental Disorders by the American Psychiatric Association (Fifth Edition).
- Endo trained its sales representatives to falsely distinguish addiction from "pseudo-addiction," which it defined as a condition in which patients exhibit drug-seeking behavior that resembles but is not the same as addiction. Endo's vice president for pharmacovigilance and risk management testified that he was not aware of any research validating the concept of pseudo-addiction.

340. On June 9, 2017, the FDA asked Endo to voluntarily cease sales of Opana ER after determining that the risks associated with its abuse outweighed the benefits. According to Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, the risks include "several serious problems," including "outbreaks of HIV and Hepatitis C from sharing the drug

[175] *Id.*
[176] *Id.* at 7.

after it was extracted by abusers" and "a serious disease outbreak."[177] If Endo did not comply, the FDA stated that it "intends to take steps to formally require its removal by withdrawing approval."[178]

341. Like Purdue and Endo, Janssen was the subject of an FDA enforcement action that identified its marketing statements as misrepresentations. For example, on February 15, 2000, the FDA sent Janssen a letter concerning the alleged dissemination of "homemade" promotional pieces that promoted Duragesic in violation of the Federal Food, Drug, and Cosmetic Act.

342. In a subsequent letter dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance."[179] The March 30, 2000 letter identified specific violations, including misrepresentations that Duragesic had a low potential for abuse:

> You present the claim, "Low abuse potential!" This claim suggests that Duragesic has less potential for abuse than other currently available opioids. However, this claim has not been demonstrated by substantial evidence. Furthermore, this claim is contradictory to information in the approved product labeling (PI) that states, "Fentanyl is a Schedule II controlled substance and can produce drug dependence similar to that produced by morphine." Therefore, this claim is false or misleading.[180]

343. The March 30, 2000 letter also stated that the promotional materials represented that Duragesic was "more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence."[181] Specifically, the FDA stated that Janssen was marketing

[177] FDA News Release, *FDA Requests Removal of Opana ER for Risks Related To Abuse*, U.S. Food & Drug Admin. (June 8, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm.
[178] *Id.*
[179] NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutica (Mar. 30, 2000) at 2.
[180] *Id.*
[181] *Id.*

Duragesic for indications other than the treatment of chronic pain that cannot otherwise be managed, for which it was approved:

> You present the claim, "It's not just for end stage cancer anymore!" This claim suggests that Duragesic can be used for any type of pain management. However, the PI for Duragesic states, "Duragesic (fentanyl transdermal system) is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by lesser means...." Therefore, the suggestion that Duragesic can be used for any type of pain management promotes Duragesic[] for a much broader use than is recommended in the PI, and thus, is misleading. In addition, the suggestion that Duragesic can be used to treat any kind of pain is contradictory to the boxed warning in the PI. Specifically, the PI states,
>
> BECAUSE SERIOUS OR LIFE-THREATENING HYPOVENTILATION COULD OCCUR, DURAGESIC® (FENTANYL TRANSDERMAL SYSTEM) IS CONTRAINDICATED:
>
> - In the management of acute or post-operative pain, including use in outpatient surgeries. . . .[182]

344. The March 30, 2000 letter also stated Janssen failed to adequately present "contraindications, warnings, precautions, and side effects with a prominence and readability reasonably comparable to the presentation of information relating to the effectiveness of the product."[183] The letter provided:

> Although this piece contains numerous claims for the efficacy and safety of Duragesic, you have not presented any risk information concerning the boxed warnings, contraindications, warnings, precautions, or side effects associated with Duragesic's use . . .. Therefore, this promotional piece is lacking in fair balance, or otherwise misleading, because it fails to address important risks and restrictions associated with Duragesic therapy.[184]

345. On September 2, 2004, the U.S. Department of Health and Human Services sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic,"

[182] *Id.* at 2-3.
[183] *Id.* at 3.
[184] *Id.*

including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products."

346. The September 2, 2004 letter warned Janssen regarding its claims that Duragesic had a low reported rate of mentions in the Drug Abuse Warning Network ("DAWN") as compared to other opioids. The letter stated that the claim was false or misleading because the claim was not based on substantial data and because the lower rate of mentions was likely attributable to Duragesic's lower frequency of use compared to other opioids listed in DAWN:

> The file card presents the prominent claim, "Low reported rate of mentions in DAWN data," along with Drug Abuse Warning Network (DAWN) data comparing the number of mentions for Fentanyl/combinations (710 mentions) to other listed opioid products, including Hydrocodone/combinations (21,567 mentions), Oxycodone/combinations (18,409 mentions), and Methadone (10,725 mentions). The file card thus suggests that Duragesic is less abused than other opioid drugs.
>
> This is false or misleading for two reasons. First, we are not aware of substantial evidence or substantial clinical experience to support this comparative claim. The DAWN data cannot provide the basis for a valid comparison among these products. As you know, DAWN is not a clinical trial database. Instead, it is a national public health surveillance system that monitors drug-related emergency department visits and deaths. If you have other data demonstrating that Duragesic is less abused, please submit them.
>
> Second, Duragesic is not as widely prescribed as other opioid products. As a result, the relatively lower number of mentions could be attributed to the lower frequency of use, and not to a lower incidence of abuse. The file card fails to disclose this information.[185]

347. The September 2, 2004 letter also detailed a series of unsubstantiated false or misleading claims regarding Duragesic's effectiveness. The letter concluded that various claims made by Janssen were insufficiently supported, including:

[185] Warning Letter from Thomas W. Abrams, U.S. Department of Health and Human Services, to Ajit Shetty, Janssen Pharmaceutica, Inc. 2 (Sept. 2, 2004), http://psychrights.org/drugs/12195RisperdalWarningLetter.pdf.

- "Demonstrated effectiveness in chronic back pain with additional patient benefits, . . . 86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep."
- "All patients who experienced overall benefit from DURAGESIC would recommend it to others with chronic low back pain."
- "Significantly reduced nighttime awakenings."
- "Significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index."
- "Significant improvement in physical functioning summary score."
- "Significant improvement in social functioning."[186]

348. In addition, the September 2, 2004 letter identified "outcome claims [that] are misleading because they imply that patients will experience improved social or physical functioning or improved work productivity when using Duragesic." The claims include "1,360 loaves . . . and counting,' '[w]ork, uninterrupted,' '[l]ife, uninterrupted,' '[g]ame, uninterrupted,' '[c]hronic pain relief that supports functionality,' '[h]elps patients think less about their pain,' and '[i]mprove[s] . . . physical and social functioning." The September 2, 2004 letter stated: "Janssen has not provided references to support these outcome claims. We are not aware of substantial evidence or substantial clinical experience to support these claims."[187]

349. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan N.V. The advisory noted that the FDA had been "examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch" and

[186] *Id.* at 2-3.
[187] *Id.* at 3.

noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic meant to treat chronic pain that does not respond to other painkillers.[188]

350. Finally, Cephalon has been the subject of investigations and enforcement actions for its misrepresentations concerning Actiq. For example, in October 2000, Cephalon acquired the worldwide product rights to Actiq and began marketing and selling Actiq in the United States. The FDA explicitly stated that Actiq "must not be used in opioid non-tolerant patients," was contraindicated for the management of acute or postoperative pain, could be deadly to children and was "intended to be used only in the care of opioid-tolerant cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain."[189] The FDA also required that Actiq be provided only in compliance with a strict risk management program that explicitly limited the drug's direct marketing to the approved target audiences, defined as oncologists, pain specialists, their nurses, and office staff.[190]

351. Cephalon purchased the rights to Fentora, an even faster-acting tablet formulation of fentanyl, from Cima Labs, and submitted a new drug application to the FDA in August 2005. In September 2006, Cephalon received FDA approval to sell this faster-acting version of Actiq; but once again, concerned about the power and risks inherent to fentanyl, the FDA limited Fentora's approval to the treatment of BTP in cancer patients who were already tolerant to around-the-clock opioid therapy for their underlying, persistent cancer pain. Cephalon began marketing and selling Fentora in October 2006.

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[188] Institute for Safe Medication Practices *New Fentanyl Warnings: More Needed to Protect Patients* (2005), https://www.medscape.com/viewarticle/510963.
[189] *Id.*
[190] *See* John Carreyrou, *Narcotic 'Lollipop' Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006), https://www.wsj.com/articles/SB116252463810112292.

352. Due to the FDA's restrictions, Actiq's consumer base was limited, as was its potential for growing revenue. In order to increase its revenue and market share, Cephalon needed to find a broader audience and thus began marketing Actiq to treat headaches, back pain, sports injuries and other chronic, non-cancer pain and targeting non-oncology practices, including, but not limited to, pain doctors, general practitioners, migraine clinics, anesthesiologists and sports clinics. It did so in violation of applicable regulations prohibiting the marketing of medications for off-label use and in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

353. Beginning in or about 2003, former Cephalon employees filed four whistleblower lawsuits claiming the company had wrongfully marketed Actiq for unapproved, off-label uses. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of the U.S. Department of Health and Human Services and agreed to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil).

354. According to a DOJ press release, Cephalon trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak to physicians about off-label uses of the three drugs, and funded CMEs to promote off-label uses. Specifically, the DOJ stated:

> From 2001 through at least 2006, Cephalon was allegedly promoting [Actiq] for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy. Cephalon also promoted Actiq for use in patients who were not yet opioid-tolerant, and for whom it could have life-threatening results.[191]

[191] Press Release, U.S. Dep't of Justice, *Pharmaceutical Company Cephalon To Pay $425 Million For Off-Label Drug Marketing* (Sept. 29, 2008), https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf.

355. Then-acting U.S. Attorney Laurie Magid commented on the dangers of Cephalon's unlawful practices:

> This company subverted the very process put in place to protect the public from harm, and put patients' health at risk for nothing more than boosting its bottom line. People have an absolute right to their doctors' best medical judgment. They need to know the recommendations a doctor makes are not influenced by sales tactics designed to convince the doctor that the drug being prescribed is safe for uses beyond what the FDA has approved.[192]

356. Upon information and belief, documents uncovered in the government's investigations confirm that Cephalon directly targeted non-oncology practices and pushed its sales representatives to market Actiq for off-label use. For instance, the government's investigations confirmed:

- Cephalon instructed its sales representatives to ask non-cancer doctors whether they have the potential to treat cancer pain. Even if the doctor answered "no," a decision tree provided by Cephalon instructed the sales representatives to give these physicians free Actiq coupons;
- Cephalon targeted neurologists in order to encourage them to prescribe Actiq to patients with migraine headaches. Cephalon sales representatives utilized the assistance of outside pain management specialists when visiting non-cancer physicians to pitch Actiq. The pain management specialist would falsely inform the physician that Actiq does not cause patients to experience a "high" and carries a low risk of diversion toward recreational use;
- Cephalon set sales quotas for its sales and marketing representatives that could not possibly have been met solely by promoting Actiq for its FDA-approved indication;

[192] *Id.*

- Cephalon promoted the use of higher doses of Actiq than patients required by encouraging prescriptions of the drug to include larger-than-necessary numbers of lozenges with unnecessarily high doses of fentanyl; and
- Cephalon promoted Actiq for off-label use by funding and controlling CME seminars that promoted and misrepresented the efficacy of the drug for off-label uses such as treating migraine headaches and for patients not already opioid-tolerant.[193]

357. The FDA's letters and safety alerts, the DOJ and state investigations and the massive settlement seemed to have had little impact on Cephalon, as it continued its deceptive marketing strategy for both Actiq and Fentora.

358. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid-tolerant had been prescribed Fentora and death or life-threatening side effects had resulted. The FDA warned: "Fentora should not be used to treat any type of short-term pain."[194]

359. Nevertheless, in 2008, Cephalon pushed forward to expand the target base for Fentora and filed a supplemental drug application requesting FDA approval of Fentora for the treatment of non-cancer BTP. In the application and supporting presentations to the FDA, Cephalon admitted both that it knew the drug was heavily prescribed for off-label use and that the drug's safety for such use had never been clinically evaluated.[195] An FDA advisory committee noted that Fentora's existing risk management program was ineffective and stated that Cephalon would have to institute a risk evaluation and mitigation strategy for the drug before the FDA would

[193] John Carreyrou, *Cephalon Used Improper Tactics to Sell Drug, Probe Finds*, Wall St. J., Nov. 21, 2006, at B1.
[194] Public Health Advisory, U.S. Food & Drug Admin., *Important Information for the Safe Use of Fentora (fentanyl buccal tablets)* (Sept. 26, 2007), https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051273.htm.
[195] U.S. Food & Drug Admin., *FENTORA (fentanyl buccal tablet) CII, Joint Meeting of Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committee* (May 6, 2008), https://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4356s2-03-Cephalon.pdf.

consider broader label indications. In response, Cephalon revised Fentora's label and medication guide to add strengthened warnings.

360. But in 2009, the FDA once again informed Cephalon that the risk management program was not sufficient to ensure the safe use of Fentora for already approved indications.

361. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case."[196] Rather, Fentora was only indicated for those who were already opioid tolerant. It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

362. Flagrantly disregarding the FDA's refusal to approve Fentora for non-cancer BTP and its warning against marketing the drug for the same, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq.

363. The misrepresentations disseminated by the Pharmaceutical Defendants and other members of the Opioid Marketing Enterprise caused Plaintiff to suffer injuries and losses and to incur costs associated with the opioid epidemic caused by the Opioid Marketing Enterprise.

364. The Pharmaceutical Defendants made the misrepresentations outlined above and throughout this Complaint intentionally and knowingly and with the specific intent to defraud Plaintiff, other hospitals, health care providers, patients, and the American public as a whole.

D. DAMAGES

[196] Letter from Michael Sauers, Regulatory Review Officer, Division of Drug Marketing, Advertising and Communications, to Carole S. Marchione, Senior Director and Group Leader, Regulatory Affairs (Mar. 26, 2009).

365. There is a grave and immediate threat of continuing and ongoing wrongful conduct and harm by the Pharmaceutical Defendants, who have paid massive fines and penalties (some of which are set forth herein), but whose subsequent actions evidence that fines and penalties are merely a cost of doing business in an industry that generates billions of dollars in revenue.

366. Plaintiff has and continues to incur operational costs, consisting of expending time and incurring expenses, in diagnosing, testing, and otherwise treating the patients impacted by the Pharmaceutical Defendants' conduct.

367. The Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff has incurred increased costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference. But for the Pharmaceutical Defendants' conduct, Plaintiff would not have suffered the damages alleged herein.

368. Plaintiff seeks all legal and equitable relief as allowed by law, including, inter alia, actual damages; treble damages; equitable and/or injunctive relief, including corrective statements, information and education, requiring divestiture by, and reasonable restrictions upon, the future activities of the Pharmaceutical Defendants, and/or forfeiture, as deemed proper by the Court; attorney's fees and all costs; expenses of suit; pre- and post-judgment interest; and all other relief sought the Court deems just and applicable. (18 U.S.C. § 1964(c)).

Count II: Violation of Racketeer Influenced and Corrupt Organizations Act,

18 U.S.C. § 1961, *et seq.*
(The "Opioid Diversion Enterprise")
(Against All Defendants)

369. Plaintiff incorporates all allegations contained in this Complaint as if fully set forth herein.

370. Plaintiff, as a "person" who has been injured within the meaning of 18 U.S.C. § 1964(c), brings this claim for civil remedies under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), against all Defendants, each of whom is a "person" within the meaning of 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

371. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt."

372. Section 1962(d) of RICO makes it unlawful "for any person to conspire to violate" section 1962(c).

373. Recognizing that there is a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970.[197] The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals.[198] Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.[199] Congress was concerned with the

[197] Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, No. 12-cv-185 (D.D.C. Feb. 10, 2012), ECF No. 14-2.
[198] *See* H.R. Rep. No. 91-1444, pt. 1 (1970).
[199] *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. §§ 801(20), 821-824, 827, 880; H.R. Rep. No. 91-1444.

diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market."[200] Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.[201] All registrants – manufacturers and distributors alike – must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion.[202] When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse.[203] The result is the scourge of addiction that has occurred.

374. Central to the closed-system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs."[204] When evaluating production quotas, the DEA was instructed to consider the following information:

- Information provided by the U.S. Department of Health and Human Services;
- Total net disposal of the basic class by all manufacturers;
- Trends in the national rate of disposal of the basic class;
- An applicant's production cycle and current inventory position;

[200] *See* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015, https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf.
[201] *See* Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012, https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf.
[202] *Id*.
[203] Joseph T. Rannazzisi Decl., *supra* note 197, ¶ 10.
[204] H.R. Rep. No. 91-1444; *see also* Testimony of Joseph T. Rannazzisi, *supra* note 200.

- Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and
- Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.[205]

375. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA, or (2) in excess of a quota assigned to it by the DEA.[206]

376. The Defendants formed an enterprise and engaged in a scheme to unlawfully increase sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute (the "Opioid Diversion Enterprise").

A. THE OPIOID DIVERSION ENTERPRISE

377. The term "enterprise" is defined as including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4).

378. The Defendants formed an association-in-fact enterprise for the purpose of unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute.

[205] *See* Testimony of Joseph T. Rannazzisi, *supra* note 200.
[206] *Id.* (citing 21 U.S.C. 842(b)).

379. In support of the Opioid Diversion Enterprise's common purpose and fraudulent scheme, the Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase, in the necessary quotas. The Defendants conducted their pattern of racketeering activity throughout the United States, including in Chicago, Illinois, through the Opioid Diversion Enterprise.

380. The Opioid Diversion Enterprise consisted of all Defendants.

381. The Opioid Diversion Enterprise was a successful endeavor for the participants. The opioid epidemic has its origins in the mid-1990s when, between 1997 and 2007, per capita purchase of methadone, hydrocodone, and oxycodone increased 13-fold, 4-fold, and 9-fold, respectively. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the country with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[207] On information and belief, the Opioid Diversion Enterprise has been ongoing for at least the last decade.[208]

382. The Opioid Diversion Enterprise has been conducting business uninterrupted since its genesis. However, it was not until recently that federal and state regulators finally began to unravel the extent of the Opioid Diversion Enterprise and the toll that it exacted on the American public.

383. The Opioid Diversion Enterprise is an ongoing and continuing organization that created and maintained systematic links and interpersonal relationships and engaged in a pattern of predicate acts (i.e. racketeering activity) in order to further the common purpose and fraudulent scheme of the enterprise to profit from the unlawful sale of prescription opioids by increasing the

[207] Keyes, et al., *supra* note 15.
[208] Matthew Perrone & Wider, *supra* note 117.

quotas governing the manufacture and sale of these controlled substances. In order to achieve that goal, the Defendants knowingly allowed suspicious orders of controlled substances to occur unhindered while millions of opioid doses were diverted into illegal markets. The end result of this strategy was exactly as the Defendants intended – artificially increased quotas for the manufacture and distribution of opioids, all of which resulted in a national opioid epidemic.

384. Each of the entities who formed the Opioid Diversion Enterprise is a person within the meaning of 18 U.S.C. § 1962(c) and acted to enable the common purpose and fraudulent scheme of the Opioid Diversion Enterprise.

385. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each Defendant; (b) was separate and distinct from the pattern of racketeering in which the Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Defendants; (d) was characterized by interpersonal relationships among the Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.

386. At all relevant times, the Opioid Diversion Enterprise was engaged in, and its activities affected, interstate and foreign commerce.

387. Within the Opioid Diversion Enterprise, there were interpersonal relationships and common communication by which the Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The members of the Opioid Diversion Enterprise used their interpersonal relationships and

communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

388. Each of the Defendants had systematic links to each other through joint participation in trade industry organizations, contractual relationships and continuing coordination of activities. The Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein. While the Defendants participated in, and are members of, the Opioid Diversion Enterprise, they each have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

389. In addition to their systematic links to and personal relationships with each other, described herein, the Defendants had systematic links to and personal relationships with each other through their participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities, including, but not limited to, the Pain Care Forum ("PCF") and the Healthcare Distribution Alliance ("HDA").

390. The PCF has been described as a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

391. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[209] Specifically, PCF members spent over $740

[209] *Id.*

million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[210]

392. Not surprisingly, each of the Defendants who stood to profit from expanded prescription opioid use is a member of and/or participant in the PCF.[211] In 2012, membership and participating organizations included the HDA (of which all Defendants are members), Endo, Purdue, Actavis (i.e., Allergan) and Teva (the parent company of Cephalon).[212]

393. Each of the Pharmaceutical Defendants worked together through the PCF to advance the interests of the enterprise. But, the Pharmaceutical Defendants were not alone. The Distributor Defendants actively participated, and continue to participate, in the PCF, at a minimum, through their trade organization, the HDA.[213] Upon information and belief, the Distributor Defendants participated directly in the PCF as well.

394. Additionally, the HDA led to the formation of interpersonal relationships and an organization between the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Pharmaceutical Defendants named in this Complaint, including Actavis (i.e., Allergan), Endo, Purdue, Mallinckrodt and Cephalon, were members of the HDA.[214] Additionally, the HDA and each of the Distributor Defendants eagerly sought the active membership and participation of the

[210] *Id.*
[211] Pain Care Forum, *supra* note 119.
[212] *See supra*, note 120.
[213] *See* Pain Care Forum, *supra* note 119. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc. and the Executive Vice President and Group President for AmerisourceBergen Corporation. *Executive Committee*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/executive-committee (last accessed Apr. 26, 2019).
[214] *Manufacturer Membership*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/membership/manufacturer (last accessed Apr. 26, 2019).

Pharmaceutical Defendants by advocating for the many benefits of members, including "strengthening . . . alliances."[215]

395. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "network[] with HDA wholesale distributor members," take advantage of "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners" and "make connections."[216] It appears that the HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and "alliances" between the Pharmaceutical Defendants and the Distributor Defendants.

396. The application for manufacturer membership in the HDA further indicates the level of connection between the Defendants and the level of insight that they had into each other's businesses.[217] For example, the manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

397. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. And, manufacturer members were asked to identify their "most recent year end net sales" through wholesale

[215] Healthcare Distribution Alliance, *Manufacturer Membership: Membership Benefits*, https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en.
[216] *Id.*
[217] Healthcare Distribution Alliance, *Manufacturer Membership Application*, https://www.hda.org/~/media/pdfs/membership/manufacturer-membership-application.ashx?la=en.

distributors, including the Distributor Defendants AmerisourceBergen, Cardinal Health and McKesson and their subsidiaries.

398. The closed meetings of the HDA's councils, committees, task forces and working groups provided the Pharmaceutical Defendants and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

399. The HDA also offered a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Pharmaceutical Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers . . . to hold strategic business discussions on the most pressing industry issues."[218] The conferences also gave the Pharmaceutical Defendants and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[219] The HDA and its conferences were significant opportunities for the Defendants to interact at a high level of leadership. It is clear that the Pharmaceutical Defendants embraced this opportunity by attending and sponsoring these events.[220]

400. Third, the Defendants maintained their interpersonal relationships by working together, through contractual chargeback arrangements, to exchange sales information and drive the unlawful sales of their opioids. To this end, the Pharmaceutical Defendants engaged in an industry-wide practice of paying rebates to the Distributor Defendants for sales of prescription opioids.[221]

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[218] *Business and Leadership Conference – Information for Manufacturers*, *supra* note 123.
[219] *Id.*
[220] *2015 Distribution Management Conference and Expo*, *supra* note 124.
[221] Bernstein & Higham, *supra* note 97; *see also*, Letter from Sen. Claire McCaskill (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png; Letters from Sen. Claire McCaskill (Mar. 28, 2017), https://www.mccaskill.senate.gov/opioid-investigation; *Purdue Managed Markets*, Purdue Pharma, http://www.purduepharma.com/payers/managed-markets/ (last accessed Sept. 14, 2017).

401. For example, the Washington Post reported that "[o]n Aug. 23, 2011, DEA supervisors met with Mallinckrodt executives at the agency's headquarters in Arlington, Va., the day a rare 5.8-magnitude earthquake hit the Washington region. People involved in the case still call the gathering 'the earthquake meeting.' DEA officials showed the company the remarkable amounts of its oxycodone going to distributors and the number of arrests being made for oxycodone possession and distribution on the street, according to one participant in the meeting who also spoke on the condition of anonymity because the case is pending."[222]

402. "Three weeks after the Aug. 23 meeting, Mallinckrodt notified 43 of its distributors that they would no longer receive rebates from the company if they continued to supply certain pharmacies whose orders appeared to be suspicious."[223]

403. "On Nov. 30, 2011, the DEA served a subpoena on Mallinckrodt, demanding documents related to its suspicious-order-monitoring program, according to the company's filings with the Securities and Exchange Commission. The subpoena brought a windfall of information. The DEA gained access to data from Mallinckrodt's rebate or 'chargeback' program, an industrywide practice that provides reimbursements to wholesale distributors. That information and other records showed where Mallinckrodt's oxycodone was going – from the company to its network of distributors to retailers down the chain."[224]

404. In addition, the Distributor Defendants and Pharmaceutical Defendants participated, through the HDA, in webinars and other meetings designed to exchange detailed

[222] Bernstein & Higham, *supra* note 97.
[223] *Id.*
[224] *Id.*

information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices and invoices.[225]

405. On information and belief, the Pharmaceutical Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

406. The contractual relationships among the Defendants also include vault security programs. The Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Upon information and belief, the manufacturers negotiated agreements whereby the manufacturers installed security vaults for distributors in exchange for agreements to maintain minimum sales performance thresholds. Upon information and belief, these agreements were used by the Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

407. Taken together, the interaction and length of the relationships between and among the Pharmaceutical Defendants and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Pharmaceutical Defendants and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the PCF are but two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrate that the leaders of each of the Defendants were in communication and cooperation.

[225] *See Webinars*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/resources/webinar-leveraging-edi (last accessed Apr. 26, 2019).

408. The foregoing evidences that Defendants were each willing participants in the Opioid Diversion Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Opioid Diversion Enterprise's purpose.

409. The scheme devised and implemented by the Defendants, as members of the Opioid Diversion Enterprise, amounted to a common course of conduct intended to increase the Defendants' sales from prescription opioids by fraudulently increasing the quotas set by the DEA and engaging in efforts to constrain the DEA's authority to hold the Defendants liable for disregarding their duty to prevent diversion. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

B. THE CONDUCT OF THE OPIOID DIVERSION ENTERPRISE

410. During the time period described in this Complaint, the Defendants conducted or participated, directly or indirectly, in the conduct of the Opioid Diversion Enterprise's affairs, within the meaning of 18 U.S.C. § 1962(c), through their membership in the PCF and the HDA and their contractual relationships, as outlined above.

411. The Defendants exerted control over the Opioid Diversion Enterprise and participated in the operation or management of the affairs of the Opioid Diversion Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

- The Defendants disseminated false and misleading statements to state and federal regulators claiming that (1) the quotas for prescription opioids should be increased; (2) they were complying with their obligations to maintain effective controls against diversion of

their prescription opioids; (3) they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids; (4) they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and (5) they did not have the capability to identify suspicious orders of controlled substances despite their possession of national, regional, state and local prescriber- and patient-level data that allowed them to track prescribing patterns over time, which the Defendants obtained from data companies, including but not limited to: IMS Health, QuintilesIMS, Iqvia, fPharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the "Data Vendors").

412. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[226]

413. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely to divert

[226] *See HDMA Is Now the Healthcare Distribution Alliance*, Pharm.Commerce (June 13, 2016), https://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/ (updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-deaslowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcementslowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: 'We Had no Leadership' in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html.

prescription opioids.[227] On information and belief, the "know your customer" questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy bought from other distributors and the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities and cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

414. The Defendants purchased nationwide, regional, state and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors' information purchased by the Defendants allowed them to view, analyze, compute and track their competitors' sales, and to compare and analyze market share information.[228] For example:

- IMS provided the Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.[229]
- Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants with

[227] *See HDMA Is Now the Healthcare Distribution Alliance*, Pharm.Commerce (June 13, 2016), https://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/ (updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-deaslowed-enforcement-while
-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opio*
id Crisis, Wash. Post (Mar. 6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcementslowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent*

charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.[230]

415. This information allowed the Defendants to track and identify instances of overprescribing.[231] In fact, one of the Data Venders' experts testified that a manufacturer of "narcotic analgesics" used the Data Venders' information to track, identify, report and halt suspicious orders of controlled substances.[232]

416. The Defendants were, therefore, collectively aware of the suspicious orders that flowed daily from their manufacturing and distribution facilities.

417. The Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[233] and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders – all for failure to report suspicious orders.[234]

: 'We Had no Leadership' in WV Amid Flood of Pain Pills, Charleston Gazette-Mail (Feb. 18, 2017), https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html.
6, 2017), https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcementslowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: 'We Had no Leadership' in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail (Feb. 18, 2017), https://www.wvgazettemail.com/news/health/dea-agent-we-had-no-leadership-in-wv-amid-flood/article_928e9bcd-e28e-58b1-8e3f-f08288f539fd.html.
led substances." *Id.* at 38.

[232] *Id.* at 38. Eugene "Mick" Kolassa testified as an expert on behalf of the Data Vender stating that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product." *Id.; see also* Joint Appen. Vol. II, *supra* note 230, at *204.

[233] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

[234] *Id.*

418. The Defendants' scheme had a decision-making structure driven by the Pharmaceutical Defendants and corroborated by the Distributor Defendants. The Pharmaceutical Defendants worked together to control the state and federal government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion and identify suspicious orders and report them to the DEA.

419. The Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was pro-opioid. The Pharmaceutical Defendants and Distributor Defendants did this through their participation in the PCF and HDA.

420. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas, and Procurement Quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

421. The scheme devised and implemented by the Defendants amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion and was designed and operated to ensure the continued unlawful sale of controlled substances.

C. PATTERN OF RACKETEERING ACTIVITY

422. Each of the Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a "pattern of racketeering activity," as defined in 18 U.S.C. § 1961(5) and as prohibited by 18 U.S.C. § 1962(c).

423. The Defendants' common purpose and fraudulent scheme violated RICO in a number of ways. The Defendants engaged in multiple, repeated and continuous violations of the

federal mail and wire fraud statutes, 18 U.S.C. §§ 1341, 1343, as well as feloniously manufactured, imported, received, concealed, bought sold, and/or otherwise dealt in controlled substances in a manner punishable under the laws of the United States, each of which constitutes a predicate act of racketeering activity pursuant to 18 U.S.C. § 1961(1).

424. The Defendants committed, conspired to commit, and/or aided and abetted others in the violation of at least two predicate acts of racketeering activity (as outlined above) within a ten-year period.

425. The multiple acts of racketeering activity that the Defendants committed, conspired to commit, and/or aided and abetted others in violation of were related to each other and posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity."

426. The Defendants committed these predicate acts intentionally and knowingly with the specific intent to advance the Opioid Diversion Enterprise.

427. The predicate acts all had the purpose of generating significant revenue and profits for the Defendants while Plaintiff was left with substantial injury to its business through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme. The predicate acts were related and not isolated events.

428. The last predicate act occurred within ten years of the commission of a prior predicate act.

429. The Defendants used the United States mail service and interstate wires to send and receive thousands of communications, representations, statements, electronic transmissions,

concealments, omissions, and payments to carry out the fraud of the Opioid Diversion Enterprise, as outlined below and throughout this Complaint.

430. Each of the Defendants knows and has known for decades that if it does not report, investigate or halt suspicious orders, the likelihood of the DEA learning of these illicit transactions and diversions in a timely manner, or at all, is greatly reduced and, therefore, is likely to contribute to the increase and maintenance of artificially high quotas.

431. Each of the Defendants also knows, and has known for decades, that the quotas for its opioid products will decrease or increase as the number of licit prescriptions decrease or increase.

432. The Opioid Diversion Enterprise worked to scale back regulatory oversight by the DEA that could interfere with the Defendants' ability to distribute their opioid drugs throughout the United States and in communities serviced by Plaintiff, including in Chicago, Illinois.

433. The Defendants' common purpose and fraudulent scheme to unlawfully increase the DEA quotas violated RICO in a number of ways.

434. The Defendants' fraudulent conduct, practices and representations include, inter alia:

a. Requests for higher aggregate production quotas, individual production quotas and procurement quotas to support the Defendants' manufacture and distribution of controlled substances they knew were being or would be unlawfully diverted;

b. Misrepresentations to facilitate the Defendants' DEA registrations;

c. Misrepresentations and misleading omissions in the Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;

d. Misrepresentations and misleading omissions in documents and communications related to the Defendants' mandatory DEA reports;

e. Rebate and chargeback arrangements between the Pharmaceutical Defendants and the Distributors Defendants that were used to facilitate the manufacture and sale of controlled substances the Defendants knew were being or would be unlawfully diverted;

f. Misrepresentations claiming that the Defendants were complying with their federal and state duties to identify, investigate and report suspicious orders of prescription opioids and/or diversion of prescription opioids into the illicit market;

g. Misrepresentations claiming that the Defendants were complying with their federal and state duties to maintain effective controls against diversion of their prescription opioids; and

h. Misrepresentations regarding the safety features of the Defendants' order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids and compliance with federal and state reporting regulations.

435. The Opioid Diversion Enterprise also engaged in efforts to constrain the DEA's authority to hold the Defendants liable for disregarding their duty to prevent diversion. Members of the PCF and HDA lobbied for the passage of legislation to weaken the DEA's enforcement authority. To this end, the Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations.[235] The HDA and other members of the PCF contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees

[235] *See supra*, note 226.

and political parties. Upon information and belief, the PCF and HDA and their members poured millions into such efforts.

436. The Defendants also feloniously manufactured, imported, received, concealed, bought, sold and/or otherwise dealt in controlled substances in a manner punishable under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4)(a) makes it unlawful "to furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed under this subchapter."[236] 21 U.S.C. § 823 requires manufacturers and distributors such as the Defendants to maintain "effective controls against diversion of particular controlled substances and any controlled substance," and 21 C.F.R. § 1301.74(b) requires CSA registrants such as the Defendants to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." Thus, pursuant to the CSA and attendant regulations, the Defendants were required to make truthful reports to the DEA of any suspicious orders and make accurate representations to the DEA regarding the operation of their monitoring programs.

437. Instead, the Defendants knowingly and intentionally furnished false and fraudulent information in, and/or omitted material information from, the reports and records submitted to the DEA. The reports and records were demonstrably false, as confirmed by investigations and enforcement actions against the Defendants such as the following:

a. The DEA targeted Mallinckrodt in 2011 about its failure to report suspicious orders of pills, as many as 500 million of which ended up in Florida between 2008 and 2012.

[236] Violation of 21 U.S.C. § 843(a)(4)(a) is a felony. *See* 21 U.S.C. § 843(d)(1) (making a violation punishable by up to four years in prison).

Federal prosecutors summarized the case by saying that everyone at Mallinckrodt knew what was going on but did not think they had a duty to report it.[237]

b. A *Los Angeles Times* investigation in 2016 uncovered that Purdue was aware of a pill mill operating in Los Angeles but failed to alert the DEA.[238] Purdue had been tracking a surge in prescriptions in Los Angeles, and a Purdue sales manager spoke with company officials in 2009 about contacting the DEA about one particular prescriber. Despite the internal tracking and discussion, Purdue did not tell authorities what it knew or cut off supply to the prescriber until several years later, when the subject clinic was out of business and its leaders had been criminally indicted.

c. The DEA and DOJ began investigating McKesson in 2013 regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson admitted to violating the CSA in a Form-8-K announcing a settlement with the DEA and DOJ.[239]

438. Because the Defendants disguised their participation in the Opioid Diversion Enterprise and worked to keep the Opioid Diversion Enterprise's existence secret so as to give the false appearance that they were complying with their federal and state obligations to identify and report suspicious orders of prescription opioids while instead allowing millions of doses of prescription opioids to be diverted into the illicit drug market, many of the precise dates of the Opioid Diversion Enterprise's uses of the United States mail and interstate wires (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged

[237] Bernstein & Higham, *supra* note 97.
[238] Harriet Ryan, et. al., *More Than 1 Million OxyContin Pills Ended Up In the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times (July 10, 2016), https://www.latimes.com/projects/la-me-oxycontin-part2/.
[239] *McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims*, McKesson (Jan. 17, 2017), https://www.mckesson.com/about-mckesson/newsroom/press-releases/2017/mckesson-finalizes-settlement-with-doj-and-dea-to-resolve-past-claims/.

without access to the Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Diversion Enterprise depended upon secrecy.

439. Despite the Defendants' concealment, Plaintiff has described above and throughout this Complaint the types of misrepresentations and material omissions the Defendants made regarding their duties to identify and report suspicious orders of prescriptions opioids and diversion of prescription opioids into the illicit market, and how those acts were in furtherance of the scheme. Plaintiff has also offered representative examples of the Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA.

440. The misrepresentations disseminated by members of the Defendants caused Plaintiff to suffer injuries and losses and to incur costs associated with the opioid epidemic caused by the Opioid Diversion Enterprise.

441. The Defendants made the misrepresentations outlined above and throughout this Complaint intentionally and knowingly and with the specific intent to defraud Plaintiff, other hospitals, health care providers, patients, the government, and the American public as a whole.

D. DAMAGES

442. There is a grave and immediate threat of continuing and ongoing wrongful conduct and harm by the Defendants, who have paid massive fines and penalties (some of which are set forth herein), but whose subsequent actions evidence that fines and penalties are merely a cost of doing business in an industry that generates billions of dollars in revenue.

443. Plaintiff has and continues to incur operational costs, consisting of expending time and incurring expenses, in diagnosing, testing, and otherwise treating the patients impacted by Defendants' conduct.

444. The Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff injury in its business and property because Plaintiff has incurred increased costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference. But for the Defendants' conduct, Plaintiff would not have suffered the damages alleged herein.

445. Plaintiff seeks all legal and equitable relief as allowed by law, including, inter alia, actual damages; treble damages; equitable and/or injunctive relief, including corrective statements, information and education, requiring divestiture by, and reasonable restrictions upon, the future activities of the Pharmaceutical Defendants, and/or forfeiture, as deemed proper by the Court; attorney's fees and all costs; expenses of suit; pre- and post-judgment interest; and all other relief sought the Court deems just and applicable. (18 U.S.C. § 1964(c)).

Count III: Violation of Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.*
(Income Derived From Racketeering)
(Against All Defendants)

446. Plaintiff incorporates all allegations contained in this Complaint as if fully set forth herein.

447. Plaintiff, as a "person" who has been injured within the meaning of 18 U.S.C. § 1964(c), brings this claim for civil remedies under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), against all Defendants, each of whom is a "person" within the meaning of 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

448. Section 1962(a) of RICO makes it unlawful "for any person who has received any income derived, directly or indirectly, from a pattern of racketeering activity . . . to use or invest, directly or indirectly, any part of such income, or the proceeds of such income, in acquisition of

any interest in, or the establishment or operation of, any enterprise which is engaged in, or the activities of which affect, interstate or foreign commerce.

449. Section 1962(d) of RICO makes it unlawful "for any person to conspire to violate" section 1962(a).

450. The term "enterprise" is defined as including "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4).

451. The Defendants are each legal entities within the meaning of 18 U.S.C. § 1961(4).

452. The Defendants are each engaged in interstate and/or foreign commerce.

453. As outlined extensively in Counts I and II of this Complaint, which are expressly incorporated herein, the Defendants engaged and/or conspired to engage in a pattern of racketeering activity with the actual, unlawful purpose of facilitating an intentional scheme to defraud Plaintiff and others.

454. The Defendants received income, directly and indirectly, from the pattern of racketeering outlined above – namely, the billions of dollars of revenue the Defendants generated and received from the sale of opioids during the time period described in this Complaint.

455. Upon information and belief, the Defendants invested the income derived from their unlawful scheme, directly or indirectly, in themselves, as enterprises, in violation of 18 U.S.C. § 1962(a).

456. The Defendants' use of their unlawfully derived funds, and their investment of those funds in themselves, furthered the Defendants' ability to continue perpetuating their fraud and creating the necessary conditions for the U.S. opioid epidemic, as described in this Complaint.

457. The Defendants' use of their unlawfully derived funds, and their investment of those funds in themselves, caused Plaintiff injury in its business and property because Plaintiff has incurred increased costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference. But for the Defendants' conduct, Plaintiff would not have suffered the damages alleged herein.

Count IV: Violation of Illinois Consumer Fraud and Deceptive Business Practices Act – 815 ILCS 505/1 (The "Opioid Marketing Enterprise") (Against the Pharmaceutical Defendants)

458. Plaintiff incorporates all allegations contained in this Complaint as if fully set forth herein.

459. The Illinois Consumer Fraud and Deceptive Business Practices Act is comprehensive legislation designed to protect consumers, borrowers, and businessmen against fraud, unfair methods of competition, and unfair or deceptive practices in the conduct of trade or business. 720 ILCS 5/33G-5(a)

460. The Illinois Consumer Fraud and Deceptive Business Practices Act creates a cause of action to prevent a deceptive act or practice by the defendants. 720 ILCS 5/33E-17

461. The Illinois Consumer Fraud and Deceptive Business Practices Act was created for occurrences where defendants intended plaintiff to rely on the deception. 720 ILCS 5/33G-2

462. The Illinois Consumer Fraud and Deceptive Business Practices Act applies where the deception occurred in the course of conduct involving trade or commerce, and actual damages to the plaintiff proximately caused by the deception. 720 ILCS 5/33G-3(b)(1)

463. The Pharmaceutical Defendants formed an enterprise – the Opioid Marketing Enterprise outlined above – and engaged in a scheme to unlawfully increase their profits and sales,

and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term, chronic pain, in violation of 720 ILCS 5/33G-5(a), and/or conspired to do so, in violation of 720 ILCS 5/33G-2.

464. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference all allegations regarding the Opioid Marketing Enterprise, as outlined extensively in Count I and elsewhere in this Complaint, including all allegations regarding the definition of the Opioid Marketing Enterprise, the conduct of the Opioid Marketing Enterprise, the pattern of racketeering activity engaged in by the Pharmaceutical Defendants, and Plaintiff's damages caused thereby.

465. Each of the Pharmaceutical Defendants conducted and participated in the conduct of the affairs of the Opioid Marketing Enterprise through a "pattern of racketeering activity", as defined in 720 ILCS 5/33G-2.

466. The Pharmaceutical Defendants conducted and participated in the conduct of the Opioid Marketing Enterprise's affairs by engaging in a pattern of racketeering activity as defined in 720 ILCS 5/33G-2.

467. The Pharmaceutical Defendants committed, conspired to commit and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 720 ILCS 5/33G-2), within a five-year period. The multiple acts of racketeering activity that the Pharmaceutical Defendants committed, or aided and abetted in the commission of, were related to each other and posed a threat of continued racketeering activity and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Pharmaceutical Defendants' regular use of the facilities, services, distribution channels and employees of the Opioid Marketing Enterprise.

468. The Pharmaceutical Defendants participated in the conduct of the Opioid Marketing Enterprise and shared in the common purpose of marketing opioids for chronic pain through a pattern of racketeering activity by knowingly making material misrepresentations or omissions to Illinois prescribers, consumers, the general public, regulators and Plaintiff. All of the misrepresentations made by members of the Opioid Marketing Enterprise furthered the common purpose of the Opioid Marketing Enterprise.

469. The Pharmaceutical Defendants committed these predicate acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the Opioid Marketing Enterprise by conducting activities prohibited by 720 ILCS 5/33G-2.

470. The predicate acts all had the purpose of generating significant revenue and profits for the Pharmaceutical Defendants while Plaintiff was left with substantial injury to its business through the damage that the prescription opioid epidemic caused. The predicate acts were committed or caused to be committed by the Pharmaceutical Defendants through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme. The predicate acts were related and not isolated events.

471. The Pharmaceutical Defendants aided and abetted others in the violations of 720 ILCS 5/33G-2, while sharing the same criminal intent as the principals who committed those violations, thereby rendering them indictable as principals in the offenses.

472. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

Count V: Violation of Illinois Consumer Fraud and Deceptive Business Practices Act – 815 ILCS 505/1
(The "Opioid Diversion Enterprise")
(Against All Defendants)

473. Plaintiff incorporates all allegations contained in this Complaint as if fully set forth herein.

474. The Illinois Consumer Fraud and Deceptive Business Practices Act is comprehensive legislation designed to protect consumers, borrowers, and businessmen against fraud, unfair methods of competition, and unfair or deceptive practices in the conduct of trade or business. 720 ILCS 5/33G-5(a)

475. The Illinois Consumer Fraud and Deceptive Business Practices Act creates a cause of action to prevent a deceptive act or practice by the defendants. 720 ILCS 5/33E-17

476. The Illinois Consumer Fraud and Deceptive Business Practices Act was created for occurrences where defendants intended plaintiff to rely on the deception. 720 ILCS 5/33G-2

477. The Illinois Consumer Fraud and Deceptive Business Practices Act applies where the deception occurred in the course of conduct involving trade or commerce, and actual damages to the plaintiff proximately caused by the deception. 720 ILCS 5/33G-3(b)(1)

478. The Defendants formed an enterprise – the Opioid Diversion Enterprise outlined above – and engaged in a scheme to unlawfully increase sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute, in violation of 720 ILCS 5/33G-2.

479. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference all allegations regarding the Opioid Diversion Enterprise, as outlined extensively in Count II and elsewhere in this Complaint, including all allegations regarding the definition of the Opioid Diversion Enterprise, the conduct of the Opioid Diversion Enterprise, the

pattern of racketeering activity engaged in by the Defendants, and Plaintiff's damages caused thereby.

480. As described throughout this Complaint, the Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise's affairs by engaging in a pattern of racketeering activity as defined in 720 ILCS 5/33G-2.

481. The Defendants committed, conspired to commit and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (i.e. violations of 720 ILCS 5/33G-2), within a five-year period. The multiple acts of racketeering activity that the Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise.

482. The Defendants participated in the conduct of the Opioid Diversion Enterprise and shared in the common purpose of marketing opioids for chronic pain through a pattern of racketeering activity by knowingly making material misrepresentations or omissions to Illinois prescribers, consumers, the general public, regulators, and Plaintiff. All of the misrepresentations made by members of the Opioid Diversion Enterprise furthered the common purpose of the Opioid Diversion Enterprise.

483. The Defendants committed these predicate acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the Opioids Diversion Enterprise by conducting activities prohibited by 720 ILCS 5/33G-2.

484. The predicate acts all had the purpose of generating significant revenue and profits for the Defendants while Plaintiff was left with substantial injury to its business through the

damage that the opioid epidemic caused. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme. The predicate acts were related and not isolated events.

485. The Defendants aided and abetted others in the violations of 720 ILCS 5/33G-2 while sharing the same criminal intent as the principals who committed those violations, thereby rendering them indictable as principals in the offenses.

486. The Opioid Diversion Enterprise worked to scale back regulatory oversight by the DEA that could interfere with the Defendants' ability to distribute their opioid drugs throughout the United States and in communities serviced by Plaintiff, including Chicago, Illinois. To distribute controlled substances in Chicago, Illinois and communities serviced by Plaintiff, the Defendants had to be able to demonstrate possession of a current DEA registration. Even if they held a current registration, the Defendants' ability to obtain a Chicago, Illinois registration could be jeopardized by past suspension or revocation of their DEA registration.

487. Defendants' racketeering activities also included violations of the 720 ILCS 5/33G-2, and each act is chargeable or indictable under the laws of Illinois and punishable by imprisonment for more than one year.[240]

488. Under Illinois law 720 ILCS 570/100, it is unlawful to "intentionally traffic" – i.e., to manufacture, distribute, sell or possess with intent to distribute – prescription opioids, which are Schedule II controlled substances that are narcotic drugs.

489. The Defendants intentionally trafficked in prescription opioid drugs, in violation of Illinois law, by manufacturing, selling and/or distributing those drugs in Chicago, Illinois in a manner not authorized by 720 ILCS 570/100. The Defendants failed to act in accordance with 720

[240] 720 ILCS 5/33G-2.

ILCS 570/100 because they did not act in accordance with registration requirements as provided in that Act.

490. Defendants did not comply with 21 U.S.C. § 823 and its attendant regulations (e.g., 21 C.F.R. § 1301.74), which are incorporated into Illinois state law, or the Illinois Pharmacy Board regulations. The Defendants failed to furnish notifications required under 720 ILCS 570/100.

491. On information and belief, the Defendants failed to furnish required notifications and make reports as required by Illinois law as part of a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA, as required by 21 C.F.R. § 1301.74, throughout the United States.

492. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

Count VI: Violation of Racketeering Act, 720 ILCS 5/33G-2
(Income Derived From Racketeering)
(Against All Defendants)

493. Plaintiff incorporates all allegations contained in this Complaint as if fully set forth herein.

494. Plaintiff, as a "person" who has sustained injury, brings this claim for civil remedies under 720 ILCS 5/33G-2.

495. The Illinois Consumer Fraud and Deceptive Business Practices Act is comprehensive legislation designed to protect consumers, borrowers, and businessmen against fraud, unfair methods of competition, and unfair or deceptive practices in the conduct of trade or business. 720 ILCS 5/33G-5(a)

496. The Illinois Consumer Fraud and Deceptive Business Practices Act creates a cause of action to prevent a deceptive act or practice by the defendants. 720 ILCS 5/33E-17

497. The Illinois Consumer Fraud and Deceptive Business Practices Act was created for occurrences where defendants intended plaintiff to rely on the deception. 720 ILCS 5/33G-2

498. The Illinois Consumer Fraud and Deceptive Business Practices Act applies where the deception occurred in the course of conduct involving trade or commerce, and actual damages to the plaintiff proximately caused by the deception. 720 ILCS 5/33G-3(b)(1)

499. As outlined extensively in Counts I–V of this Complaint, which are expressly incorporated herein, the Defendants engaged and/or conspired to engage in a pattern of racketeering activity with the actual, unlawful purpose of facilitating an intentional scheme to defraud Plaintiff and others.

500. The Defendants received proceeds, directly and indirectly, from the pattern of racketeering outlined above – namely, the billions of dollars of revenue the Defendants generated and received from the sale of opioids during the time period described in this Complaint.

501. Upon information and belief, the Defendants used or invested the proceeds derived from their unlawful scheme, directly or indirectly, in the establishment or operation of themselves, as enterprises, in violation of 720 ILCS 5/33G-2.

502. The Defendants' use of their unlawfully derived funds, and their investment of those funds in themselves, furthered the Defendants' ability to continue perpetuating their fraud and creating the necessary conditions for the U.S. opioid epidemic, as described in this Complaint.

503. The Defendants' use of their unlawfully derived funds, and their investment of those funds in themselves, caused Plaintiff injury in its business and property because Plaintiff has incurred increased costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference. But for the Defendants' conduct, Plaintiff would not have suffered the damages alleged herein.

Count VII: Negligence

504. Plaintiff incorporates all allegations contained in this Complaint as if fully set forth herein.

505. The Defendants owed a duty to use ordinary care, or that care that a reasonable person would use under circumstances similar to those shown by the evidence. The Defendants' general duty owed to Plaintiff rests upon the Defendants activities manufacturing, marketing, distributing and selling opioids in the geographic areas served by Plaintiff.

506. In manufacturing, marketing, distributing and selling opioids, a highly dangerous and addictive drug, Defendants had a duty to act as a reasonable person and take precautions to avoid unreasonable risks and injury to others, including Plaintiff.

507. A reasonably prudent manufacturer and distributor would have, or should have, anticipated the scourge of opioid addition and that it would wreak havoc on communities and leave healthcare providers holding the bill for providing lifesaving and expensive care for those who became addicted to Defendants' drugs.

508. Defendants breached the duty they owed to Plaintiff as outlined above and incorporated herein by failing to warn of the significant risks posed by prescription opioids, by failing to warn the medical community and the public of the risks of addiction, by turning a blind eye to known suspicious orders of prescription opioids and by failing to report known pill mills, among others things.

509. Defendants' breach of the duty they owed to Plaintiff resulted in foreseeable damages. Plaintiff provided uncompensated and undercompensated care and treatment to those injured as a result of the prescription opioid crisis.

510. Plaintiff is also entitled to punitive damages as the Defendants knew or should have known, in light of the surrounding circumstances, that their actions would naturally and probably result in injury or damage, yet the Defendants acted in reckless disregard of the consequences, from which malice may be inferred.

Count VIII: Strict Products Liability

511. Plaintiff incorporates all allegations contained in this Complaint as if fully set forth herein.

512. At all times pertinent to this cause of action, the Defendants were engaged in the business of manufacturing, assembling, selling and distributing opioids. All Defendants were in the chain of distribution of one or more of the opioid products discussed herein.

513. At the time that the Defendants manufactured and sold the drugs, the opioids contained defects in their design that made them unreasonably dangerous and unfit for their intended use. These defects include, but are not limited to, defect in design, defect in the manufacturing process, defect in marketing by improper, inadequate instructions and failure to warn of the dangers of the product.

514. Notwithstanding the Defendants' claims of the safety of the drugs and that they were not addictive, it is now clear that opioids are highly addictive, incredibly destructive and unreasonably dangerous.

515. The design defect proximately caused injury and damages to Plaintiff. The design defect in opioids rendered the product dangerous to an extent beyond that which would be contemplated by the ordinary and reasonable buyer of the drug.

516. The Defendants are strictly liable for the injuries suffered by Plaintiff caused by the design defect in opioids. Plaintiffs' injuries and losses are continuing in nature.

Count IX: Violation of the Illinois Consumer Fraud and Deceptive Business Practices Act - 815 ILCS 505/1

517. Plaintiff incorporates all allegations contained in this Complaint as if fully set forth herein.

518. The Illinois Consumer Fraud and Deceptive Business Practices Act is comprehensive legislation designed to protect consumers, borrowers, and businessmen against fraud, unfair methods of competition, and unfair or deceptive practices in the conduct of trade or business. 720 ILCS 5/33G-5(a)

519. The Illinois Consumer Fraud and Deceptive Business Practices Act creates a cause of action to prevent a deceptive act or practice by the defendants. 720 ILCS 5/33E-17

520. The Illinois Consumer Fraud and Deceptive Business Practices Act was created for occurrences where defendants intended plaintiff to rely on the deception. 720 ILCS 5/33G-2

521. The Illinois Consumer Fraud and Deceptive Business Practices Act applies where the deception occurred in the course of conduct involving trade or commerce, and actual damages to the plaintiff proximately caused by the deception. 720 ILCS 5/33G-3(b)(1)

522. At all relevant times, the Pharmaceutical Defendants, directly, and/or through their control of third parties, and/or by aiding and abetting third parties, violated consumer protection laws, as set forth above, by making and disseminating untrue, false and misleading statements to promote the sale and use of opioids to treat chronic pain to health care providers, prescribers and consumers who presented at Plaintiff's facility addicted to and/or overdosing on Defendants' drugs, or by causing untrue, false and misleading statements about opioids to be made or disseminated in order to promote the sale and use of opioids to treat chronic pain to health care providers, prescribers and consumers who presented at Plaintiff's facility addicted to and/or

overdosing on Defendants' drugs. By virtue of the acts alleged herein, the Pharmaceutical Defendants engaged in methods, acts and practices with the intent to defraud health care providers and prescribers. These untrue, false and misleading statements included, but were not limited to:

a. Misrepresenting the truth about how opioids lead to addiction;

b. Misrepresenting that opioids improve function;

c. Misrepresenting that addiction risk can be managed;

d. Misleading medical providers and patients through the use of misleading terms like "pseudo-addiction";

e. Falsely claiming that withdrawal is simply managed;

f. Misrepresenting that increased doses pose no significant additional risks; and

g. Falsely omitting or minimizing the adverse effects of opioids and overstating the risks of alternative forms of pain treatment.

523. As set forth herein, the Distributor Defendants also committed repeated and willful unfair or deceptive acts or practices in the conduct of commerce.

524. As set forth herein, each Distributor Defendant failed to report and/or prevent the diversion of highly addictive prescription drugs to illegal sources.

525. Because of the dangerously addictive nature of these drugs, the Distributor Defendants' marketing, sales and/or distribution practices unlawfully caused an opioid and heroin plague and epidemic. Each Distributor Defendant had a non-delegable duty to guard against and prevent the diversion of prescription opioids to other than legitimate medical, scientific and industrial channels.

526. The Distributor Defendants failed to disclose the material facts that, inter alia, they were not in compliance with laws and regulations requiring that they maintain a system to prevent

diversion, protect against addiction and severe harm and specifically monitor, investigate, report and refuse suspicious orders. But for these material factual omissions, the Distributor Defendants would not have been able to sell opioids, and the Distributor Defendants would not have been able to receive and renew licenses to sell opioids.

527. As set forth above, the Distributor Defendants' deceptive trade practices specifically include, but are not necessarily limited to, the following:

a. The practice of not monitoring for suspicious orders of prescription opioids;

b. The practice of not detecting suspicious orders of prescription opioids;

c. The practice of not investigating suspicious orders of prescription opioids;

d. The practice of filling, or failing to refuse fulfillment of, suspicious orders of prescription opioids;

e. The practice of not reporting suspicious orders of prescription opioids;

f. The practice of rewarding increases in prescription opioid sales; and/or

g. The practice of falsely misrepresenting to the public that Defendants were complying with their legal obligations.

528. The Distributor Defendants' unfair and deceptive actions, concealments and omissions were reasonably calculated to deceive.

529. As described more specifically above, the Distributor Defendants' representations, concealments and omissions constitute a willful course of conduct which continues to this day.

530. The damages which Plaintiff seeks to recover were sustained as a direct and proximate cause of the Defendants' intentional and/or unlawful actions and omissions.

531. The Defendants' actions and omissions in the course of marketing, selling and/or distributing opioids constitute deceptive trade practices under consumer protection laws.

532. The Defendants egregiously, knowingly, willfully and/or unlawfully engaged in the deceptive trade practices described herein.

533. The Defendants' unfair practices, as described above, violated public policies, under both federal law (21 U.S.C. § 823, 21 U.S.C. § 801; 21 C.F.R. 1301.74) and state law, to maintain effective controls against diversion and to monitor, detect, investigate, refuse to fill and report suspicious orders of prescription opioids originating from the communities served by Plaintiff, as well as those orders which the Defendants knew or should have known were likely to be diverted into the communities served by Plaintiff. Nevertheless, by engaging in the conduct alleged above, the Defendants actively worked to conceal the risk of addiction related to opioids from patients and prescribers in the hopes of selling greater quantities of their dangerous drugs. The Defendants also worked to undermine public policy, enshrined by regulations contained in state and federal law, that is aimed at ensuring honest marketing and safe and appropriate use of pharmaceutical drugs.

534. As set forth herein, all Defendants have violated the CSA. Each violation of the CSA is also a violation of the Illinois Controlled Substances Act. 720 ILCS 570/100

535. The Defendants egregiously, knowingly and willfully engaged in the deceptive trade practices described herein.

536. The Unfair Practices Act permits an action to recover actual damages to be brought by any person (including any legal entity) who suffers an ascertainable loss of money or property as a result of the unfair or deceptive method or practice proscribed by the Unfair Practices Act. 815 ILCS 505/1

537. Plaintiff has been damaged, and is likely to be further damaged in the future, by the deceptive trade practices described herein.

538. Plaintiff is entitled to treble damages under the Unfair Practices Act, 815 ILCS 505/1, as a result of Defendants' willful engagement in the proscribed trade practices described herein.

Count X: Unjust Enrichment

539. Plaintiff incorporates all allegations contained in this Complaint as if fully set forth herein.

540. To prevail on a claim for unjust enrichment, "one must show that: (1) another has been knowingly benefitted at one's expense (2) in a manner such that allowance of the other to retain the benefit would be unjust." 815 ILCS 505/1

541. Defendants have unjustly retained a benefit to Plaintiff's detriment, and the Defendants' retention of the benefit violates the fundamental principles of justice, equity and good conscience.

542. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within the communities served by Plaintiff, including in Chicago, Illinois, including from opioids foreseeably and deliberately diverted within and into the communities served by Plaintiff.

543. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

544. Plaintiff has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

545. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

546. These expenditures have helped sustain the Defendants' businesses.

547. Plaintiff has conferred a benefit upon the Defendants by paying for the Defendants' externalities: the cost of the harms caused by the Defendants' improper distribution practices.

548. Plaintiff has conferred a benefit upon the Defendants by preserving the lives of patients who continue to consume and demand more opioids, creating increased demand and profits for the Defendants.

549. The Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

550. Plaintiff has paid for the cost of the Defendants' externalities, and the Defendants have benefited from those payments because the payments allowed the Defendants to continue providing customers with a high volume of opioid products. The cost of the Defendants' wrongful conduct in selling and distributing opioids includes, inter alia, increased healthcare services and addiction treatment for opioid users. These costs are part of the Defendants' business, yet the Defendants are not paying for them – Plaintiff is. By using Plaintiff to fund the Defendants' negative externalities (i.e., the cost of the harms caused by their wrongful practices), the Defendants knowingly saved on expenses, thereby allowing them to sell and distribute more opioids, and make more money, than if they had internalized the actual cost of their activities. The Defendants have thereby received a benefit unjustly financed by Plaintiff.

551. Because of their deceptive marketing of prescription opioids, the Pharmaceutical Defendants obtained enrichment they would not otherwise have obtained. Because of their conscious failure to exercise due diligence in preventing diversion, the Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification, and Plaintiff lacks a remedy provided by law.

552. The Defendants have unjustly retained benefits to the detriment of Plaintiff, and the Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

553. The Defendants' misconduct alleged herein is ongoing and persistent.

554. The Defendants' misconduct alleged herein does not concern a discrete event of the sort a healthcare provider would reasonably expect to occur, and is not part of the normal and expected costs of a healthcare provider's existence. Plaintiff alleges wrongful acts which are neither discrete nor of the sort a healthcare provider can reasonably expect.

555. By reason of the Defendants' unlawful acts, Plaintiff has been damaged and continues to be damaged, in a substantial amount to be determined at trial.

556. Plaintiff seeks an order compelling the Defendants to disgorge all unjust enrichment to Plaintiff and awarding such other, further, and different relief as the Court may deem just.

Count XI: Negligent Misrepresentation

557. Plaintiff incorporates all allegations contained in this Complaint as if fully set forth herein.

558. Plaintiff seeks recovery of economic damages, which were the foreseeable result of the Defendants' unlawful actions and omissions.

559. Each Defendant had an obligation to exercise reasonable care in marketing, selling and/or distributing highly dangerous opioid drugs within the geographic areas serviced by Plaintiff, including in Chicago, Illinois.

560. Each Defendant had an obligation to exercise due care in marketing, selling and distributing highly dangerous opioid drugs within the geographic areas served by Plaintiff including in Chicago, Illinois.

561. Each Defendant owed a duty to Plaintiff, and to the public served by Plaintiff, because the injury was foreseeable, and in fact foreseen, by the Defendants.

562. Reasonably prudent manufacturers and/or distributors of prescription opioids would have anticipated that the scourge of opioid addiction would wreak havoc on communities, and the significant costs which would be imposed upon the hospital entities associated with those communities, such as those serviced by Plaintiff, including in Chicago, Illinois. The closed system of opioid distribution whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, and wherein all links in the chain have a duty to prevent diversion, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

563. The escalating amounts of addictive drugs flowing through Defendants' businesses, and the sheer volume of these prescription opioids, further alerted the Defendants that addiction was fueling increased consumption and that legitimate medical purposes were not being served.

564. As described above in allegations expressly incorporated herein, the Distributor Defendants breached their duties to exercise due care in the business of wholesale distribution of dangerous opioids, which are Schedule II Controlled Substances, by failing to monitor for, failing to report and filling highly suspicious orders time and again. Because the very purpose of these duties was to prevent the resulting harm – diversion of highly addictive drugs for non-medical purposes – the causal connection between the Distributor Defendants' breach of duties and the ensuing harm was entirely foreseeable.

565. As described elsewhere in the Complaint in allegations expressly incorporated herein, the Distributor Defendants misrepresented their compliance with their duties under the law and concealed their noncompliance and shipments of suspicious orders of opioids, in addition to other misrepresentations alleged and incorporated herein.

566. The Defendants breached their duties to prevent diversion and report and halt suspicious orders, and they misrepresented their compliance with their legal duties.

567. The causal connection between the Defendants' breaches of their duties and misrepresentations and the ensuing harm was entirely foreseeable.

568. The Defendants' breaches of their duties and misrepresentations were a cause-in-fact of Plaintiff's injuries.

569. The risk of harm to Plaintiff and the harm caused were within the scope of protection afforded by the Defendants' duty to exercise due and reasonable care in marketing, selling and/or distributing highly dangerous opioid drugs in the geographic areas serviced by Plaintiff, including in Chicago, Illinois. The Defendants' substandard conduct was a legal cause of Plaintiffs' injuries.

570. The Defendants' unlawful and/or intentional actions as described herein create a rebuttable presumption of negligence and negligent misrepresentation under state law.

571. As described above in allegations expressly incorporated herein, the Defendants' breaches of duty and misrepresentations caused, bears a causal connection with and/or proximately resulted in the damages sought herein.

Count XII: Fraud

572. Plaintiff incorporates all allegations contained in this Complaint as if fully set forth herein.

573. As alleged herein, the Defendants made false representations and concealed material facts about opioids.

574. The Defendants made misrepresentations and failed to disclose material facts to Plaintiff, physicians and consumers throughout the United State to induce the physicians to

prescribe and administer, and to induce consumers to purchase and consume, opioids as set forth herein.

575. The Defendants' false representations and omissions were material and were made and omitted intentionally or recklessly.

576. The Defendants intended that Plaintiff, physicians and consumers would rely upon their misrepresentations and omissions.

577. Plaintiff, its agents and persons on whom Plaintiff and its agents rely, did in fact rightfully, reasonably and justifiably rely on the Defendants' representations and/or concealments both directly and indirectly. Plaintiff's injuries were directly and proximately caused by this reliance.

578. Plaintiff, physicians and consumers reasonably relied on the Defendants' misrepresentations and omissions. Physicians prescribed and administered, and consumers purchased and consumed, opioids as set forth herein.

579. Because of reliance on the Defendants' misrepresentations and omissions of material fact, Plaintiffs have suffered monetary damages as set forth herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff LORETTO HOSPITAL OF CHICAGO, requests that the Court grant the following relief:

A. That proper process issue and be served on the Defendants and that they be required to appear and answer the Complaint within the time prescribed by law;

B. That the Court find the Defendants liable for violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.*, violations of the 720 ILCS 5/33G-2,

negligence, strict products liability, violations of 815 ILCS 505/1, unjust enrichment, negligent misrepresentation, and fraud;

C. That the Court award Plaintiff its damages in an amount to be proven at trial;

D. That the Court award Plaintiff pre-judgment and post-judgment interest;

E. That the Court award Plaintiff punitive damages;

F. That the Court award treble damages as available;

G. That the Court award Plaintiff its reasonable attorneys' fees and costs;

H. That the costs of this action be taxed to the Defendants; and

I. That the Court award Plaintiff such other, further and general relief at law or in equity that the Court deems appropriate.

J. Plaintiff seeks a trial by jury for all counts so triable.

Respectfully submitted by:

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